

**EVALUATION OF THE  
POPULATION COUNCIL'S PROGRAMMATIC  
COOPERATIVE AGREEMENT WITH USAID**

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## ABBREVIATIONS

AVSC	AVSC International
CA	cooperating agency
CBR	Center for Biomedical Research
CLIA	laboratory certifications
CTO	Cognizant Technical Officer
CTU	Contraceptive Technology Update
DFID	British Department for International Development
EC	emergency contraception
ECC	Expanding Contraceptive Choice program
EE	ethynylestradiol
EPI	Expanded Program on Immunization
FDA	U.S. Food and Drug Administration
FHI	Family Health International
FINNIDA	Finnish Development Agency
FSH	follicle stimulating hormone
FY	fiscal year
GCP	good clinical practices
GFD	Gender, Family, and Development
GLP	good laboratory procedures
GnRH	gonadotropin releasing hormone
GnRH-TT	gonadotropin releasing hormone with tetanus toxoid
HIV/AIDS	human immunodeficiency virus/acquired immunodeficiency syndrome
HORIZONS	HIV Operations Research project
HRT	hormone replacement therapy
HSV	human simplex virus
ICCR	International Committee for Contraceptive Research
ICDDR	International Centre for Diarrheal Disease Research
IDRC	International Development Research Centre
IND	investigative new drug
IPD	International Programs Division
IRB	institutional review board
IUD	intrauterine device
JHPIEGO	Johns Hopkins University Program for International Education in Reproductive Health
KAP	knowledge, attitudes, and practices
LAC	Latin American and Caribbean region
LH	luteinizing hormone
LN <sub>g</sub>	Levonorgestrel
MCH-FP	Maternal Child Health and Family Planning program
MAQ	Maximizing Access and Quality initiative

MEASURE	Monitoring and Evaluation to Assess and Use Results project
MOH	Ministry of Health
N-9	nonoxynol-9
NDA	new drug application
NFP	natural family planning
NGO	nongovernmental organization
NICHD	National Institute for Child Health and Human Development
NIH	National Institutes of Health
NORPLANT®	a contraceptive method that releases the synthetic hormone levonorgestrel contained in six silastic rods
OB/GYN	obstetrics and gynecology
OC	oral contraceptive
OR	Operations Research
OR/TA	Operations Research/Technical Assistance project
PCS	Population Communications Services project
P&E	Policy and Evaluation Division, Office of Population, USAID
PHN	Center for Population, Health and Nutrition, USAID
PRD	Policy Research Division
RH	reproductive health
RTI	reproductive tract infection
SAG	Strategy Advisory Group
SIV	simian immunodeficiency virus
STD	sexually transmitted disease
UNFPA	United Nations Population Fund
VR	vaginal ring
VSC	voluntary surgical contraception
WHO	World Health Organization
USAID	U.S. Agency for International Development



## EXECUTIVE SUMMARY

The evaluation of the programmatic cooperative agreement (the agreement) with the Population Council was conducted by a four-person team between March 26 and April 15, 1998. U.S. Agency for International Development's (USAID) agreement provides support to three Council divisions: the Center for Biomedical Research (CBR), the International Programs Division (IPD), and the Policy Research Division (PRD) from September 30, 1994, to September 30, 1999. This evaluation assesses the Council's performance and makes recommendations for the remaining life of this agreement and for a follow-on agreement.

During the first four years of the agreement, USAID obligated \$33.6 million that included funding direct costs of \$12.1 million for CBR, \$10.2 million for IPD, and \$300,000 for PRD. In any one year, the agreement funds about 13 percent of the total Council budget. The majority (86 percent) of USAID funding for the agreement comes from core funds provided by the Office of Population, Bureau for Global Programs, Field Support and Research.

The activities and accomplishments supported by this agreement are many. In the area of biomedical research, the Council's program continues to be guided in part by the International Committee for Contraceptive Research (ICCR). USAID funding of the CBR's work supports the development of new methods of fertility regulation and represented 42 percent of the contraceptive development program's 1997 budget. The new leadership at CBR has had a positive impact on the program, particularly in finding corporate partners for numerous Council contraceptive products. The Council's new, more structured approach to product licensing has also been successful. The research endeavors are varied and include vaginal rings (VR); intrauterine delivery systems; transdermal gel and patch formulations for women; a product for emergency contraception; an extension of the efficacy of subdermal implants (both NORPLANT® and the Levonorgestrel 2-rod Implant System); a vaginal spermicide/microbicide formulation; and for men, an androgen implant (MENT™) and related transdermal gel and patch formulations.

The Expanding Contraceptive Choice (ECC) program in the IPD has provided a flexible mechanism to support technical assistance, applied-field-based service delivery research, and other policy-related and training activities. USAID has provided \$6.1 million to the ECC program, representing over 80 percent of its funding for the 1993 to 1997 period. (USAID funding for ECC represents 4.7 percent of the IPD budget or 12.5 percent if all other USAID funding is not counted.) The program has made many important accomplishments over the past three and one-half years. The ECC staff has played a crucial leadership role in working with public sector programs to improve the quality of family planning services in Brazil, Kenya, Tanzania, and Zambia. ECC studies have increased understanding of the role and acceptability of female condoms and the acceptability of postabortion counseling and family planning. Furthermore, ECC facilitated product approval and registration of NORPLANT® in more than a dozen countries, primarily in Africa.

ECC's many activities include (1) assisting obstetrics and gynecology (OB/GYN) associations and women's groups in India and Senegal to improve service quality and especially method mix; (2) participating along with other cooperating agencies (CA) involved Population in USAID's Maximizing Access and Quality (MAQ) initiative; and (3) working closely with the World Health Organization (WHO) Task Force on Research on the Introduction and Transfer of Technologies for Fertility Regulation in Brazil, Bolivia, Burkina Faso, Ethiopia, and Zambia. Furthermore, other Population Council staff, in collaboration with ECC, are carrying out impact studies in Senegal and Zambia to assess improvements in the quality of services.

The cooperative agreement has also funded other activities and research in the IPD, as well as research under the PRD. For the IPD program, these include (1) participation of the reproductive health (RH) program staff in meetings on integrating family planning and RH services, (2) extensive technical assistance in family planning and reproductive health in Bangladesh, and (3) the integration of STD and HIV/AIDS prevention into family planning and RH services in Africa. The agreement essentially provides a funding mechanism with good flexibility for most of these activities, which were supported by USAID missions and the Africa Bureau. However, the scope of work for this evaluation did not include assessing these activities. Support to the PRD under this agreement represents about 10 percent of the division's funding, covering expert assistance to the Navrongo Health Research Centre in Ghana and providing start-up funding for a new adolescent research program. The team finds the research supported under the agreement to be very interesting. The agreement has provided a flexible, useful mechanism for USAID offices in Washington and USAID missions to invest in new and ongoing Council work. The team fully supports USAID and the Council's decision to fund future support of the Navrongo project through the agreement.

The evaluation team finds that the Council has made progress in numerous areas that were of concern during the previous evaluation. First, the Council has improved its overall management, including its financial and computer systems. Intra-agency cooperation between CBR and ECC has improved, although further enhancement of such collaboration is suggested. The Council's improved management of the ICCR is commended, and the good management of regulatory affairs is recognized. The team's comments on the various contraceptive research projects are too numerous and specific to encapsulate here, although recommendations for continued USAID funding of particular projects are summarized in Table 1. The team is encouraged by the Council's plans to modernize its laboratory facilities. One final note on the CBR: The team concludes that funding for biomedical research appears adequate at present, but we foresee the need for additional funds if the current research program is successful.

ECC has supported a much broader range of activities related to contraceptive methods and issues in developing countries than during the previous agreement. Program staff members have been responsive to country and regional needs, and the combined expertise of medical advisors and social scientists is seen as an essential ingredient in the program. Furthermore, ECC has both contributed to and benefited from the collaborative work with the WHO Task Force on contraceptive introduction.

Within the Council, the team finds that the lack of an IPD-wide strategic plan and a well-defined role for ECC in the division has caused some confusion and inhibited good coordination and collaboration. The current composition and staffing of the ECC program is adequate for a relatively low-priority program area within the IPD. However, if the Council decides to develop an enhanced role for ECC within the division and/or as a link across divisions, the structure and staff would require changes. The lack of funding appears not to be a problem, because the level of expenditures relative to funding is not high (only 56 percent for years 1 through 3). Also, ECC was quite successful in obtaining funds both from USAID field missions and from other donors, such as WHO and the United Nations Population Fund (UNFPA) in West Africa. Assuming that ECC will be an important area for the IPD in the future, the team encourages the Council to seek more non-USAID funding for core support to give the program greater flexibility and capability.

The team observes that the relationship between USAID and the Population Council has much improved from the last evaluation and is now quite good. This is largely because of a change in CBR's leadership and the continuity and skills of the USAID technical advisor who oversees the agreement. The team suggests a few ways to improve relations with USAID missions and notes a number of potential leads for future ECC work with USAID missions.

The team's recommendations for the remainder of the current agreement are that the CBR should continue its research as proposed, and that any changes to the ECC's structure, staffing, and funding should await the outcome of an IPD review of the division's overall portfolio. Specific recommendations for dissemination of ECC findings and other ECC-related work are made in the list of recommendations and in Section 7.1.2. The team also recommends continued funding of PRD's research, but at a higher level than before.

The team's review of the proposed "Strategic Plan for 1999 to 2004" underscores the importance of USAID's continued support to the Population Council. Recommendations on the CBR's research projects are presented in the Recommendations section (Recommendations 27 to 40). The team envisages a role for ECC at the Council as a bridge between CBR's contraceptive products and their use in developing-country settings, and as an important source of assistance to contraceptive introduction (both broadly and narrowly conceived), to the MAQ initiative, and to studying social and cultural factors affecting contraceptive choice. It is of utmost importance that the proposed Strategic Plan for ECC be thoroughly vetted within the IPD and with the PRD. The team also sees the need for stronger ties between PRD and IPD, especially in developing interventions based on the PRD research.



Table 1 available in hard copy



## **RECOMMENDATIONS**

### **Contraceptive Development**

#### **Planning**

1. Regular meetings involving staff of both the contraceptive development group and the basic research group should be held. These meetings would enable all Council biomedical staff to exchange information and should facilitate progress in both contraceptive development and basic research.

#### **Monitoring**

2. It is strongly recommended that an assistant clinical research associate be hired forthwith to assist Mr. Allen, to increase the level of monitoring, and to be available to fill Mr. Allen's position if necessary.
3. Efforts should be made to facilitate more collegial and cooperative collaboration with other contraceptive research organizations, especially those supported by USAID.

#### **Collaboration with Industry**

4. The Council should strive to keep in mind one of its earliest and most commendable goals—meeting the needs of the public sector worldwide.

#### **Licensing Agreements**

5. Consideration should be given to inserting into the licensing agreements wording that would allow the Council to continue developing the products for developing countries on a separate, but parallel, track to that of the industrial partner's development for developed countries.
6. The language regarding who pays for developing country product introduction and marketing should be softened to provide alternatives for public sector involvement.

## **Expanding Contraceptive Choice**

### **Mission and Planning**

7. A mission and strategic planning exercise for ECC should be carried out within the larger context of the IPD's strategic planning and with the participation of all key program staff in the International Programs Division, the regional directors, and other Council divisions. The effort to develop comprehensive regional and country programs might improve ECC's role.
8. ECC should not be subsumed under the Operations Research (OR) program.

### **Dissemination**

9. ECC should be encouraged (1) to develop a more systematic dissemination plan, and to hire staff or a consultant to develop such a plan; (2) to identify topics or issues that should be addressed through a comprehensive or coordinated effort; and (3) to determine the most appropriate vehicles or channels for this dissemination. Dissemination should be among the topics for discussion at all upcoming ECC semiannual meetings. Also, given that numerous CAs are already involved in research on some of the contraceptive technologies, such dissemination work should draw on the combined experiences of the CA community.

### **Impact of Program Activities**

10. The impact research that has been initiated by IPD's director of policy and regional programs should be an integral part of ECC's strategic approach for country-based work. Although this model appears very useful, ECC should also consider reviewing the USAID-funded EVALUATION project experience for additional ways to assess impact.

## **Collaboration and Coordination**

### **ECC and CBR**

11. ECC should be integrally involved in Clinical Phase II programs to ensure that the products developed are relevant for underserved populations in developing countries. This would involve addressing issues of acceptability, access, and indications of benefits in low-resource settings and among special target populations (see Section 3.8.1). USAID should be willing to fund the costs of this additional involvement since it is unrealistic to expect commercial partners to fully fund this part of the Clinical Phase II program.



## ECC and IPD

12. As the IPD develops its strategic plan, one key component should involve fostering transparent exchanges and collaborative efforts among IP programs. The field staff of ECC, OR, and RH need to be a part of this planning process. Also, perhaps a certain percent of uncommitted staff time and budget could be set aside within each program for future, as-yet-undefined, collaborative opportunities.

## ECC and Other Cooperating Agencies in Population

13. The outcome of the mission and strategic planning exercise (Recommendation 7) should be communicated to potential collaborators among the CAs to improve future collaborative efforts.
14. As a follow-up to its technical assistance in revising service guidelines, ECC staff should collaborate with the new Monitoring and Evaluation to Assess and Use Results project (MEASURE) (assuming that Macro International awards a subcontract to the Council such collaboration should be relatively easy) to develop a module for the Situational Analysis that can be used to monitor and evaluate the use of new guidelines. Furthermore, greater collaboration between ECC and the Johns Hopkins University Program for International Education in Reproductive Health (JHPIEGO) in the field might also ensure that efforts to revise service delivery guidelines are routinely related to a country's training programs.

## ECC and Other Donors

15. ECC staff should continue to collaborate with WHO in implementing this strategic approach to contraceptive introduction, but should be very careful not to become overextended by taking on more countries than can reasonably be managed given existing staff constraints. If WHO sees ECC as the principal implementing arm for this approach, then WHO should consider providing core support to the ECC program if feasible. The Council should also pursue this possibility.
16. The ECC program at the Council, while benefiting from collaboration with WHO, should continue to have a broader scope that nevertheless encompasses issues related to the WHO Task Force. ECC clearly has other important program components, including the more traditional approach to contraceptive introduction where it is deemed advisable, advancement of the MAQ initiative, and other initiatives that concern social and cultural factors affecting contraceptive choice.

## Population Policy Research

17. The team finds the research supported under the agreement to be very interesting and worth continued support at a higher level than before. In addition, USAID should consider moving the review and funding of the PRD research projects to the P&E Division, unless such a move would jeopardize that source of funding under the cooperative agreement, or unless that move would restrict the investigators of the PRD because of too much USAID direction. Thus, USAID is encouraged to invest more in the division's program, which is on the cutting edge of social science research and analysis.
18. A mechanism should be created within the Council to develop and carry out appropriate intervention studies once the PRD's research has reached a point where potential programmatic implications are identified. Those activities should be supported with USAID funding.
19. The Council should consider establishing a working group involving outside expertise to help guide its social science and field research programs in both the IPD and PRD. This working group would also further collaboration with other organizations. A working group could also play a role in looking at the array of programs within the IPD and how they might be configured.

## General Administration

20. The Council should identify one highly ranked person to interact with the USAID technical advisor. This individual should handle both administrative and program issues.
21. The Council should consider special training for the legal counsel in intellectual property rights.

## Personnel

22. An established, respected scientist should be appointed director of the contraceptive development unit as soon as possible to provide more day-to-day direction and intellectual stimulation in the division since the current vice president of CBR does not have time to serve this need.
23. The CBR staff, though well motivated and skilled in their fields of interest, must be augmented. Furthermore, the highest priority should be given to recruiting women into the contraceptive development program.

## Relationship with USAID

24. The USAID Research Division should talk to USAID mission staff about making appropriate decisions on contraceptive introduction, which would reinforce the Council's advice on such matters and ensure that the best programmatic decisions are made in different countries.

## The Future

### Contraceptive Development

25. The studies proposed by CBR for the balance of this cooperative agreement should be continued.

### Follow-on Agreement

26. USAID should continue to contribute its financial support of the Population Council through a non-competitive, follow-on programmatic cooperative agreement. The Council's work in the three program areas of contraceptive development, expanding contraceptive choice, and population policy research is sufficiently unique and draws on years of institutional capability and experience. Therefore, the team sees no merit in competing a future cooperative agreement.

### Strategic Planning

27. There should be greater interaction between the basic and applied groups. (See also Recommendation 1.)

### Contraceptive Products

28. The team recommends that USAID provide funds so that the Council may apply to the U.S. Food and Drug Administration (FDA) for label changes for both the NORPLANT<sup>®</sup> and Levonorgestrel 2-rod Implant System products under the new drug applications (NDA) held by the Council.
29. If the Council's competitive position with regard to Implanon (Nestorone<sup>®</sup> single implant) does not improve significantly within a year or two, consideration should be given to dropping this project, unless a commercial partner is found.

### Contraceptive Rings

30. No further development of the Nestorone<sup>®</sup> Progestin Ring will be undertaken except with an industrial partner. The team concurs with this course of action.

Studies of the Nestorone® Progestin/Ethynylestradiol Ring will continue to determine the best dosing schedule and the optimal doses, and it is hoped that those studies will be done with a commercial partner. Those studies seem appropriate and should continue.

31. Because the lack of a suitable ring manufacturer is a serious impediment to progress in developing contraceptive rings, USAID should consider supporting this activity.

#### Intrauterine Delivery Systems

32. The team is enthusiastic about promotion of the availability of the LNG IUD, but does not recommend the continued development of the Nestorone® IUD, unless the Council is able to present valid arguments for its continuation.

#### Transdermal Delivery for Women

33. The team recommends that development of both the Nestorone® Progestin Gel for Women and the Nestorone® Patch Formulations be continued for the present, but within two years it should be possible to select the optimal formulations.

#### Emergency Contraception

34. The team has little enthusiasm for development of a Nestorone®-only patch for emergency contraception because of its seeming lack of utility. Given the efficacy of LNG (taken by itself orally), the development costs may well outweigh any benefit.

#### Spermicides/Microbicides

35. The Council has developed one formulation that seems to have promise, but future USAID funding for this work should be carefully considered because of overall funding limitations.

#### Probing Studies in Female Contraception

36. The team does not favor research on the use of anordiol for emergency contraception (EC), because the drug appears not to have any advantage over other EC regimens.

## GnRH Immunocontraceptive

37. Although results from the safety study are important for advancing knowledge about immunocontraception and should be published, no further USAID funding should be given on this specific project after completion of the ongoing safety studies, whatever the outcome.

## Androgen Implant (MENT™)

38. The Council should continue to give the highest priority to Androgen Implant (MENT™) work.

## Transdermal Delivery for Men

39. The MENT™ Gel and MENT™ Patch formulations for men will clearly be very useful for hormone replacement therapy (HRT), but whether compliance will be an issue if they are to be used for contraception is of concern. For this reason, the MENT™ implant would appear to have higher priority for USAID funds at this time.

## Probing Studies in Male Contraception

40. Modest support for one project that looks at the rearrangement of surface proteins of the sperm surface during epididymal maturation is recommended, until the identity and function of the protease are more firmly established.
41. The second project involves the resurrection of compounds that had been previously studied by the Council with National Institute for Child Health and Human Development (NICHD) support. The studies that will need USAID funding should be clearly identified. A well-defined product development plan should be established to exploit this lead. Collaboration with scientists in the product development group who previously worked on the related compound would be helpful.



# **1. INTRODUCTION**

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## **1.1 Overview**

The Population Council is a nongovernmental, nonprofit, scientific organization founded in 1952, located in New York City, and committed to the enhancement of human welfare. Its multidisciplinary work is carried out by the Center for Biomedical Research (CBR), the Policy Research Division (PRD), and the International Programs Division (IPD). The current staffing at the Council comprises more than 440 individuals.

The Population Council was founded in large part with the impetus and support of the Rockefeller Foundation and other foundations. Hence, it neither sought nor required support from governments in its beginning years. However, with the establishment of the Center for Population Research (CPR) at the National Institutes of Health (NIH), the Council sought and obtained funding for both the biomedical and social science research activities. In the early 1970s, the U.S. Agency for International Development (USAID) developed its first cooperative agreement with the Council and has consistently provided support since that time. At present, the Council's budget is about \$51 million, receiving funds from over 200 governments, multilateral organizations, foundations, corporations, and individuals; the U.S. government, primarily USAID and NIH, provides about 51 percent of the total support.

The current programmatic cooperative agreement between USAID and the Population Council (CCP-A-00-94-00013-04) provides funding for the period from September 30, 1994, to September 30, 1999. Through September 1997, \$33.6 million had been obligated to the agreement. The purpose of the agreement is to support the Population Council's programs to improve family planning technology available for use in developing countries and to improve the delivery and use of family planning services in the developing world. The three program areas of the Population Council funded under the agreement are (1) contraceptive development, through the product development subdivision in the Center for Biomedical Research; (2) the Expanding Contraceptive Choice program (ECC), through the IPD; and (3) Population Policy Research, carried out by the PRD. The agreement provided about 13 percent of the Council's total budget in 1997.

Other USAID agreements and other contracts with the Council include three agreements and contracts to conduct operations research in family planning in each of three regions: Africa, Asia, and Latin America; a cooperative agreement to carry out operations research for HIV/AIDS programs; a cooperative agreement to conduct activities related to the development of a vaginal microbicide that ended in September 1997; and separate agreements with USAID missions in Guatemala and Mali. The combined total USAID support to the Council represented 48 percent of the Council's total budget in 1997.

## **1.2 Purpose and Methodology of the Evaluation**

The purpose of this evaluation is to assess the Population Council's performance under the Programmatic Cooperative Agreement during the period from September 1994 through March 1998, and to recommend directions and activities for USAID support for the remainder of the current agreement and for a possible follow-on agreement. (A detailed scope of work for the evaluation is attached as Appendix A.) This evaluation updates a previous evaluation conducted in November 1993 by a team of four scientists, headed by Dr. Michael Harper, a member of the current team (Harper, et. al., 1993). That team's recommendations were in large part favorable. Certain detailed recommendations contained in that review will be discussed in this report.

This evaluation was carried out from March 26 to April 15, 1998, by a team of four scientists. The team included two members with expertise in contraceptive research and development and the U.S. Food and Drug Administration (FDA) approval process. Those two members assessed the work of the Center for Biomedical Research. The other two team members were a medical doctor with clinical experience and a social scientist, both of whom are knowledgeable about family planning programs in developing countries. Those two members assessed the program for Expanding Contraceptive Choice and activities of the Policy Research Division. The team interviewed USAID officials, Population Council staff, and representatives of other international agencies, including a number of cooperating agencies (CA) in the population field. In addition, the team attended the semiannual meeting of the International Committee for Contraception Research (ICCR) in New York City. One team member traveled to Brazil, where she reviewed activities in Latin America with the ECC regional medical associate for the Latin American and Caribbean region (LAC). Another member traveled to Kenya and Zambia where she met with regional medical associates for East and Southern Africa and for West Africa, and a social scientist of the ECC program based in India. Team members reviewed ECC activities in Africa and India through interviews with ECC staff and site visits in both Kenya and Zambia. (See Appendix C for the List of Contacts.)

This report presents the team's findings, comments, and recommendations on the Council's Contraceptive Development Program in Chapter 2, on the Expanding Contraceptive Choice program in Chapter 3, and on other program components of the International Programs Division and the Policy Research Division that receive USAID support through this agreement in Chapter 4. Chapter 5 reviews issues of organizational management, personnel, finances, and facilities. Chapter 6 describes the relationship between USAID and the Council for this agreement. Chapter 7 describes issues regarding the remaining life of this agreement and a follow-on agreement.



### **1.3 Changes in USAID Programs**

During the current agreement between the Population Council and USAID, numerous changes occurred in USAID's program that have had some bearing on the Council's program. First, the Office of Population broadened its focus from family planning to a more comprehensive approach to reproductive health that encompasses safe pregnancy, prevention of STD/HIV/AIDS, and the integration of family planning and health services. This broader focus, adopted largely in response to the recommendations of the 1994 International Conference on Population and Development in Cairo, has widened the scope of topics and activities that could be addressed under the current agreement. At the same time, it has also meant a less-well-defined mandate in terms of the links between family planning and other areas of reproductive health with which the Population Council has been concerned for many years.

The second change was the development of the USAID Strategic Plan for the Center for Population, Health and Nutrition (PHN) (USAID, December 1995). As part of the Clinton administration's effort to "reengineer" the federal government, the Strategic Plan defines USAID Strategic Objectives to reduce unintended pregnancies, maternal mortality, infant and child mortality, and STD transmission with a focus on HIV. All USAID-funded programs and projects in the PHN sector address these objectives and justify and report their activities in terms of specific, expected results. The "1996-97 Annual Progress Report of the Programmatic Cooperative Agreement" describes all activities in terms of the results defined in the Strategic Plan.

The third change has been the introduction of an avenue for funding activities by USAID missions called field support. Traditionally, the programmatic cooperative agreement had been funded through central or core funds from the Office of Population. Field support funds allow USAID missions to define exactly what activities are to be carried out in the given country. Furthermore, country-specific activities can only be carried out with field support, so that the onus is on the Population Council staff to develop activities in concert with USAID mission staff. The advent of field support thus represented a loss of flexibility and a greater challenge for the Population Council staff, both at headquarters and in the regions, in designing technical assistance activities and interventions to obtain USAID-mission funding.

A final change in the USAID environment has been the closing of numerous missions in Africa where ECC could have been more active. Among the missions that have closed are those in Botswana, Burkina Faso, Cameroon, Côte d'Ivoire, and Togo. Further, the USAID mission in Kenya has ceased funding all population research activities in favor of service delivery, an added constraint to carrying out work under ECC in Kenya.



## **2. CONTRACEPTIVE DEVELOPMENT**

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### **2.1 Background**

Contraceptive development has been central to the Council's mandate from its inception. Under the leadership of Warren Nelson, and then Sheldon Segal, the CBR became primarily responsible for the development and worldwide availability of modern IUDs and long-term progestin subcutaneous implants. It is difficult to overestimate the importance of these two technological contributions to human welfare. As noted below, the Council is currently developing several additional methods of fertility regulation with the goal (shared with multilaterals, governments, other not-for-profit entities, and the commercial sector) of increasing the ability of couples to control their fertility through the availability of a variety of methods.

### **2.2 Planning**

From its inception, the CBR had two components, one devoted directly to the development of new methods of fertility regulation, the other to more basic research in the reproductive sciences, which, under the leadership of Dr. Wayne Bardin, became more focused on male reproduction. Currently, contraceptive development activities are supported largely by USAID and NIH, whereas the basic science work is supported largely by NIH through a center grant, a cooperative agreement, and individual research grants (called R-01s). Other sources of support are also used.

Whereas the planning of the basic science work is largely the responsibility of the individual scientists involved, the contraceptive development work is more coordinated and cooperative. Although the ultimate scientific decisions are the responsibility of the vice president of the Center for Biomedical Research, Dr. Elof Johansson, much of the intellectual work in deriving these decisions is conducted at the biannual meetings of the ICCR (see Appendices D, E, and F) and at contraceptive development meetings, which are supposedly held "twice monthly." During the team's interviews with CBR staff, it became clear that although there is much more communication among the scientists than in the immediate past, the twice monthly meetings involving the contraceptive development group within CBR do not appear to be taking place. The team feels that these meetings are important, and that they should be attended not only by those in the contraceptive development group, but also by those in the basic research group. Not all researchers need to attend all meetings, but cross-fertilization and information exchange between groups on what is under development and what might be new leads can only be beneficial.

The ICCR is a unique organization in that it is composed of an international group of scientists, devoted to developing new contraceptives, who conduct much of the research in their own institutions, as well as collectively recommending the direction the group's work should take. At the ICCR meetings, members discuss in detail their current work and make proposals for future work.

Members of the team attended the ICCR meeting in New York on April 1 and 2, 1998. (The meeting's agenda is provided in Appendix E, and a list of attendees in Appendix F.) At the meeting, several ICCR members were asked for their opinions regarding the functioning of the ICCR under Dr. Johansson's leadership, and all said that they were impressed by the newly evident openness and spirit of congeniality. Committee members believe that they are now actively involved in decision making and that they are well informed. In addition, the time spent in the closed meeting that precedes the open part of the ICCR meeting is now being profitably used to address substantive issues rather than to rehearse for the open meeting. Further details concerning planning are given in the background information provided by the Council (see Appendix G).

### **Team Comment**

The team commends the Council for its improved management of the ICCR.

### **Recommendation**

1. Staff of both the contraceptive development group and the basic research group should meet periodically. These meetings would enable all Council biomedical staff to exchange information and should facilitate progress in contraceptive development and basic research.

## **2.3 Monitoring**

The Council carries out overall monitoring of the contraceptive development projects at the time of the biannual ICCR meetings.

Monitoring of actual clinical trials is conducted primarily by one individual, Mr. Arthur Allen, who works with and for Dr. Irving Spitz, who is in charge of clinical trials. Mr. Allen is the clinical trial monitor for all Council-sponsored clinical trials. He has 30 years experience in this field, first with industry (Ortho Pharmaceutical) and for the last 5 years with the Council. There are usually six to eight clinical trials underway at each center at a time, and the ICCR has seven main clinical centers around the world. Staff reported that the clinics have been FDA approved. Mr. Allen spends approximately one week at each center two times a year. During these visits, Mr. Allen ensures that the centers are in regulatory compliance and that required laboratory certifications (CLIA) are in order. Furthermore, during each visit Mr. Allen checks records at random and notes any deficiencies or errors, especially with respect to protocol violations and informed consent forms.

Mr. Allen is responsible for monitoring all Council studies, and he admitted that, by industry standards, the Council trials were under-monitored. Dr. Spitz also does some monitoring, but given that he has eyesight problems and that he spends 50 percent of his time in Israel, it is not clear how much assistance he can provide. Therefore, of major concern is that if Mr. Allen becomes unable to travel, there is no ready, trained assistant able to undertake this critical function. There appeared to be reluctance to ask Family Health International (FHI), a USAID CA, for monitoring assistance because of the proprietary nature of the Council studies.

## **Recommendations**

2. It is strongly recommended that an assistant clinical research associate be hired forthwith to assist Mr. Allen, to increase the level of monitoring, and to be available to fill Mr. Allen's position if necessary.
3. Efforts should be made to facilitate more collegial and cooperative collaboration with other contraceptive research organizations, especially those supported by USAID.

## **2.4 Regulatory Affairs**

If clinical trials on new products are successful, the end of these trials is application to national drug regulatory agencies for approval of these products. Dr. Frederick Schmidt is responsible for this activity. He prepares and ships documentation for clinical trials, packs and ships drugs to clinic sites, is involved with quality assurance and issues regarding "good laboratory procedures" (GLP), and interacts with the institutional review boards (IRB). Members of the ICCR were very satisfied with Dr. Schmidt's services.

### **Team Comment**

The team commends Dr. Schmidt for his management of regulatory affairs.

## **2.5 Collaboration with Industry**

### **2.5.1 Commercial Partnering**

It was clear to the team that, through the collaborative efforts of the vice president for biomedical research, Dr. Johansson, and the vice president for corporate affairs, Ms. Arnold, important steps have been made in finding corporate partners. Examples of such cooperation are as follows:

- E. Merck, Inc., received approval in Brazil in January 1998 for the use of the Nestorone<sup>®</sup> rod for the treatment of endometriosis.

- Silesia Laboratories received approval in Chile in February 1998 for the progesterone vaginal ring (VR) for contraception during lactation.
- The investigative new drug (IND) for LNG IUD has been transferred from the Population Council to Berlex Laboratories, the American subsidiary of Schering AG.

The team is encouraged by these developments in finding corporate partners. Discussions with the CBR staff did not indicate a strong interest in public sector needs. Thus, the team finds that meeting the needs of the public sector is not sufficiently prominent as an organizational goal.

## **Recommendation**

4. The Council should strive to keep in mind one of its earliest and most commendable goals—meeting the needs of the public sectors worldwide.

### **2.5.2 Licensing Agreements**

CBR's intention, as clearly enunciated by Dr. Johansson, is to find industrial partners to take over various projects, especially the Nestorone<sup>®</sup>/ethinylestradiol vaginal ring, the MENT<sup>™</sup> implant, and the Nestorone<sup>®</sup> implant. Despite USAID support, not enough funding is available to bring all these projects to fruition without an industrial partner. Dr. Johansson is to be commended for perceiving the need to move rapidly to find industrial partners. The problem is that some of the companies are more interested in the products for hormone replacement therapy (HRT) and treatment of prostate cancer than for contraception.

The advantage of having an industrial partner take over a particular project is that it requires little or no further involvement of Council staff or resources. Thus, scarce resources can be used to advance those other projects having no ready and willing partner. The disadvantage of such partnerships is that once the Council relinquishes control of the product development process, the speed at which the product goes to the market depends solely on the industrial partner, whose first priority is to market the product in developed countries—especially the United States—where the return on investment can be maximized. Consequently, the introduction of the product into developing country markets may be delayed even though, through a licensing agreement, an advantageous price for the public sector has been determined. This delay makes it difficult for the IPD to plan for the introduction of new methods when it is not clear which methods will be introduced and when they might be available.

Item 3 of the present draft "Exclusive Licensing Term Sheet"(see Appendix L) states that

The Council generally will be involved in conducting or planning trials necessary to obtain manufacture and marketing approvals for the Product, both in the U.S. and overseas. *All such studies are to be conducted at the expense of the Licensee or sub-licensee.*" [emphasis added]

In such a case, the licensee has no incentive, and even a disincentive, to proceed with studies for developing country introduction and marketing. If the most rapid availability of new products for developing countries is a major concern to USAID, then the wording of the licensing agreement should be modified to state that costs for the development and marketing of products for developing countries may be borne by the public sector, and that studies for developing country introduction will be done *pari passu* with those necessary to introduce the new product into the United States and other developed countries. Further, the agreement should stipulate that the licensee is obligated to make drug supplies, formulation details, and toxicology information available to permit this process to take place. However, the Council should not proceed to incur such costs unless they are to be explicitly reimbursed by USAID. Ultimately, the Council and/or USAID should have the right to commence studies in developing countries when appropriate, and they should not be dependent on the wishes of the commercial partner.

### **Team Comments**

The Council's new, more structured approach to product licensing under the leadership of the vice president for corporate affairs, with the assistance of the vice president of the CBR, the general counsel, and the business analyst, is to be commended. The Council's record in licensing new products to industry has been excellent, and it should continue this approach noting the following recommendations. The team commends the Council for its success in licensing products to industry.

### **Recommendations**

5. Consideration should be given to inserting into the licensing agreements wording that would allow the Council to continue developing the products for developing countries on a separate, but parallel, track to that of the industrial partner's development for developed countries.
6. The language regarding financial responsibility for developing country introduction and marketing should be softened to provide alternatives for public sector involvement.

## **2.6 Program Activities and Accomplishments**

The current status of specific projects, their impact, and the extent of collaboration are briefly reviewed in the order those subjects were discussed at the ICCR meeting in April 1998. Further details are available in the minutes of the meeting, provided in Appendix D. A more detailed discussion of each topic is described in Section 7.2.1, with recommendations for the future.

### **2.6.1 Contraceptive Rings: Nestorone<sup>®</sup>/EE, Nestorone<sup>®</sup>, Nestorone<sup>®</sup>/E2**

#### **Team Comments**

The Council has been developing contraceptive rings, also known as vaginal rings or VRs, for many years, so it is encouraging that the Silesia company recently received approval in Chile for marketing the progesterone vaginal ring for lactating women. The Nestorone<sup>®</sup>/EE device holds promise for contraception, but more work must be done to ascertain the optimal drug doses and use schedules and, although a potential manufacturer has been identified, the manufacturer has stated that it will require funds to proceed. The Nestorone<sup>®</sup>-only vaginal ring may hold promise only for lactating women because of irregular bleeding patterns. The Nestorone<sup>®</sup>/E2 device will be dropped.

### **2.6.2 Therapeutic Ring: Progesterone/E2**

#### **Team Comments**

This product is designed to provide HRT to menopausal women and therefore is not relevant to this review. The Council is to be commended, however, for its efforts in finding a commercial partner.

### **2.6.3 MENT<sup>™</sup> Implant and Gel**

#### **Team Comments**

This product has potential for both contraceptive and therapeutic use and, if success is to be achieved with either, it is more likely to occur sooner with therapeutic use. A possible commercial partner has expressed interest in the product for the treatment of hypogonadal men. The products use as a contraceptive remains in the early stages; this area of investigation remains a long-term, high-risk area of significant potential importance.



#### 2.6.4 GnRH Immunocontraceptive (Male)

##### **Team Comments**

Dr. Hunnicutt was recruited to undertake immunological safety studies on the GnRH-TT vaccine for men. There is a concern that this antigenic complex could cause auto-immune disease. As yet, only limited information is available, and in only 1 out of 20 rats was any immune complex formation (in the kidney) seen. This formation may be a chance event, since it was not correlated with level of antibody or degree of testosterone suppression. One problem that has arisen is the lack of a sustained and consistent antibody response. Dr. Tsong has arranged with Dr. Diana Blithe at the National Institute for Child Health and Human Development (NICHD) to have new GnRH antigens synthesized, which are coupled to human T-cell-stimulating epitopes to evaluate whether antigenicity can be increased. The success of this project looks singularly problematic, especially in light of the results obtained with the GnRH hydrogel, the inconsistent antibody response, the potential for autoimmune disease, and the need to return to preparing new antigenic preparations. This project should be a low priority compared to other products in the Council's portfolio. To date, this project has been funded with NICHD funds. This project need not—indeed, should not—be funded with USAID funds.

#### 2.6.5 NORPLANT® and the LNg 2-rod Implant System (NORPLANT 2)

##### **Team Comments**

Developmental research on NORPLANT® and the LNg 2-rod Implant System is essentially complete; each of these important methods of contraception has already been registered in many countries and has entered the Council's Expanding Contraceptive Choice program. Recent work has demonstrated that the efficacy of NORPLANT® may be extended from five to seven years, and the efficacy of the Levonorgestrel 2-rod Implant System may be extended from three to five years. Unfortunately, the American commercial partner is reluctant to apply to the FDA for the necessary changes in the label.

#### 2.6.6 Nestorone® Implant

##### **Team Comments**

Progress is slow in the Council's effort to produce a single implant effective for two years. Organon is well along with its single implant, Implanon, which is effective for three years.

## 2.6.7 Nestorone<sup>®</sup> Transdermal Gel and Nestorone<sup>®</sup> and Nestorone<sup>®</sup>/EE Transdermal Patches

### **Team Comments**

These projects remain in the very early stages, although a commercial partner is interested in the Nestorone<sup>®</sup> and the Nestorone<sup>®</sup>/EE patches for HRT. Somewhat less interest in the gel has been expressed by another partner.

## 2.6.8 Microbicides (Vaginal)

### **Team Comments**

The Council, through the work directed by Dr. Phillips, has joined other investigators in attempting to develop a woman-controlled vaginal product that will protect women from STDs, particularly HIV infection. Dr. Phillips is concentrating on a product that prevents pregnancy as well as infection, thus avoiding the complexities that will arise with any attempt to produce a product that prevents infection but allows pregnancy to occur. Dr. Phillips is an electronmicroscopist by training and has assembled a staff to work primarily on a product composed of seaweed products and nonoxynol-9, a well-established spermicide. His work is supported by NIH and the Mellon Foundation, and he has recently been awarded part of a five-institution grant from the Rockefeller Foundation called the Network for Basic Research on Microbicides. The team does not recommend that USAID support this project, because its work to date is narrowly focused.

### **3. EXPANDING CONTRACEPTIVE CHOICE**

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#### **3.1 Background**

Since its inception in the mid-1980s, the Council's program to expand contraceptive choice has been aimed at facilitating the widest availability and most appropriate use of contraceptive technologies developed by the Council: the Copper T 380A intrauterine device and NORPLANT<sup>®</sup> contraceptive implants. In 1992, the program was expanded to include all appropriate contraceptive technologies, not just those developed by the Council. In the Council's 1994 proposal to USAID for five years of programmatic support, this broader emphasis was further defined (Population Council, March 1994). Based on lessons learned from the introduction of NORPLANT<sup>®</sup> and the IUD, the program shifted from a focus on the introduction of a single technology to a broader assessment of the range of methods and the niches that different methods fill within a given family planning program. The Contraceptive Introduction program was thus expanded to include a comprehensive set of activities designated as Expanding Contraceptive Choice, or ECC. The program has supported technical assistance, applied field-based service delivery research, and policy-related activities. Four years after the ECC program was developed, the evaluation team assessed its evolution, accomplishments, constraints, and challenges.

ECC is one of several programs within the International Programs Division. The others include Operations Research (through three regional projects); Reproductive Health (RH); Gender, Family, and Development (GFD); and, most recently, the HIV Operations Research project (HORIZONS), an operations research project on HIV/AIDS.

#### **3.2 Mission**

When it began, ECC was described by Council staff as the bridge between CBR's research outputs—the contraceptive products—and society. No comparable unit within the Council exists that fulfills this role, and it continues to be an important one. Over the years, ECC's focus has expanded from introduction of the Council's contraceptive products to a more strategic or systems approach for broadening method mix. ECC works to expand choice not only by adding both new and existing contraceptive methods, but also by helping to achieve an appropriate method mix within the context where the services are offered, while also addressing related issues of access and quality. An appropriate method mix or use of contraceptive technologies is based on the combination of clients' needs and the capacity of the service program and the providers to meet those needs. ECC has begun to further broaden the framework of its mission to include addressing social conditions that influence individuals' ability to make meaningful contraceptive choices.<sup>1</sup>

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<sup>1</sup> The ECC's mission that is proposed in the "Strategic Plan for 1999-2004" concerns expanding beyond contraceptive technologies to "all new and underutilized technologies." The team's comment on this further

The team also looked at the relationship between ECC and other programs within the International Programs Division. It appears that the primary focus or mission of ECC versus that of the Reproductive Health program is not clear. Although RH has characterized itself as dealing with "everything except contraception," work to introduce emergency contraception, for example, is being done by RH as well as by ECC. Likewise, postpartum contraception is being addressed by both RH and ECC. Seemingly, who does what is sometimes determined as much by "who got there first" as by a clear mission.

One central question asked in this evaluation is whether ECC should become part of future work in the Operations Research (OR) program at the Council. Although these two programs have existed side-by-side at the Council for several years and do collaborate, the team finds that ECC's mission is distinct from that of the Operations Research program. Although ECC's focus is contraception introduction and choice, the scope of the Council's OR projects is centered on using a problem-solving methodology (i.e., operations research) to address a wide variety of issues related to access, quality, and sustainability of family planning and reproductive health services. A cursory review of the portfolio of projects under the Council's Africa OR/TA project shows that only about 20 percent or fewer of the projects overlap with ECC-type studies that look at access to and quality of contraceptive methods (Adamchak, et. al., 1998). Furthermore, many of the issues identified and addressed by ECC require relatively long-term technical assistance (beyond the life of a discreet OR study), locally-based medical expertise (or the combination of medical and social science expertise), and involvement with non-service delivery groups, such as feminist groups, the press, policymakers, and advocacy groups. These key characteristics of the ECC program are less typical of the OR approach. The team's interviews with numerous key informants suggest that the relative emphasis on questions of contraceptive choice and use under the future (but not yet awarded) OR cooperative agreement is likely to decrease, given the broader focus on reproductive health.

### **Team Comment**

It appears that ECC's mission has not been adequately conceptualized in relation to the other programs in the International Programs Division. (See also discussion in Section 3.4 on planning and Recommendations 7 and 8.)

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evolution is presented in Section 7.2.2.

### 3.3 Portfolio of Activities

Over the four-year period of the current agreement, ECC has supported a variety of technical assistance and training activities, as well as a range of studies and projects. Some of the studies and projects were implemented through subawards to host-country organizations; others were carried out as in-house projects implemented by ECC staff. Use of the term "project" is a simple way for the Council and USAID to refer to various sets of activities, as well as discreet activities that are supported by the agreement.

ECC's technical assistance has been in many forms:

- Participating in the development and/or refinement of national family planning guidelines (Bolivia, Brazil, Kenya, Senegal, and Zambia);
- Working with international agencies in reviewing service delivery guidelines (USAID and World Health Organization [WHO]) and in developing and implementing the Maximizing Access and Quality (MAQ) initiative (USAID and other CAs in Population); and
- Organizing and/or participating in comprehensive needs assessments of contraceptive introduction and reproductive health (Bolivia, Brazil, Burkina Faso, and Zambia, primarily with WHO and some United Nations Population Fund [UNFPA] funding).

Training activities have largely been workshops for Contraceptive Technology Updates (CTU) for policymakers tailored to the needs of a given country or setting. At least 20 of the CTU workshops have been held in different countries and regions.

ECC has supported or implemented a variety of studies to achieve the following:

- Introduce different contraceptive methods (emergency contraceptive, injectables, female condoms, diaphragm, NORPLANT<sup>®</sup>,<sup>2</sup> and IUD);
- Assess new schemes for using particular methods (natural family planning [NFP] and diaphragm);
- Assess the role of different types of service delivery staff in providing methods (nurses and paramedics providing NORPLANT<sup>®</sup>);
- Assess new counseling and contraceptive services for postabortion care (Bolivia); and

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<sup>2</sup> The Team learned that use of the IUD in Kenya has declined, although use of NORPLANT<sup>®</sup> has increased. Field staff and MOH officials are interested in studying why IUD use has declined.

- Assess the impact of improvements in the quality of family planning services (Senegal and Zambia).

ECC has also supported a number of projects or activities in different countries:

- A national dissemination workshop in Zambia to present new family planning guidelines and standards that had been developed following a joint Ministry of Health (MOH), WHO, and ECC contraceptive needs assessment;
- A series of advocacy workshops in Gujarat, India, to address barriers to contraceptive method availability and choice.

Although all of those activities were anticipated in the five-year proposal to USAID, ECC had expected to assist with the introduction of the Levonorgestrel 2-rod Implant System and a phased replacement of NORPLANT® with the new 2-rod system. This activity has not happened because of the lack of a commercial product, as discussed in Section 2.6. Furthermore, the previous evaluation had called for clarification of the role of the Population Council in terms of NORPLANT® introduction, technical assistance, and support in relationship to other CAs. This has not happened in any formal way. However, the experience in numerous countries suggests that host-country institutions continue to look at the Population Council as the lead source of assistance on NORPLANT®. Furthermore, the fact that not all Council staff favor providing NORPLANT® has led to some confusion on the part of other CAs. Introduction activities for other new methods, such as Nestorone implants and vaginal rings, were also expected, but product development was slower than anticipated and no introduction efforts were warranted.

### **Team Comments**

The diversity of activities supported and contraceptive issues addressed by ECC is impressive. ECC clearly provides a flexible mechanism for the Council to support and carry out a wide range of activities. The Council has not defined and made known (at least among other CAs) its current role on NORPLANT® introduction and support, although the demand for its technical assistance continues.

### **3.4 Planning**

The Council's five-year proposal for 1994 to 1998 describes the basic program of contraceptive introduction and expanding contraceptive choice. Each year, as part of the overall annual workplan for the Cooperative Agreement, ECC submits to USAID a list of specific activities to be supported in the coming year. The proposed activities have been identified primarily by field staff, in consultation with host-country institutions—especially ministries of health and USAID missions—and in collaboration with other donors, such as WHO and UNFPA.

The extent of regional coverage for ECC's work has been determined largely by the amount of field opportunities. Activities within one entire region, such as Asia, have been minimal, with the exception of India and the study of NORPLANT<sup>®</sup> removal in Indonesia. Opportunities to work in certain countries, such as Francophone Africa, where USAID has closed missions; Kenya, where USAID no longer funds population research; or South Africa, where USAID has no population program, have been limited by the lack of core ECC funds to explore and develop potential new avenues of work. Lack of staff has also limited the number of countries in which ECC has been able to function (e.g., no presence in countries such as Peru or Ecuador).

Collaborative planning with other programs within the International Programs Division (RH and GFD) or with other divisions (CBR and Policy Research) appears to be ad hoc and does not reflect a clear understanding of the relative roles of or a strategic plan for ECC regarding other programs within the Division or at the Council. Collaboration has depended largely on staff members' personal interests and on the ability of ECC field staff and central staff to develop collaborations. The responsibility for initiating and developing collaboration appears to have rested mostly on ECC and has met, at times, some obstacles. (See Section 3.7.2 on collaboration and coordination.)

In its presentation to the evaluation team, the IPD listed six purposes of its activities. Two of these are (1) improving reproductive health, and (2) reducing unintended pregnancies safely. Those activities are most closely related to ECC, but also to RH and OR programs. The Division is currently developing goals and objectives, presumably for a strategic plan that may help clarify the planning process. An additional level of complexity in planning comes because of the decentralized character of many of the Council's activities. Increasingly, the regional program directors within IPD are encouraged to develop comprehensive regional, if not country, programs. In India, the proposed ECC program has been drafted with input from the regional staff.

### **Team Comment**

ECC staff have done well in developing a portfolio of activities through both in-house projects and subawards. ECC has been very responsive to country and regional needs. However, because of the lack of a strategic plan within the IPD and a well-defined role for ECC within the division, its general mode has been responsive rather than proactive. A further consequence of the lack of an overall plan has been that the personnel have in large part determined the program, rather than the program having determined the personnel.

### **Recommendations**

7. A mission and strategic planning exercise for ECC should be carried out within the larger context of the IPD's strategic planning and with the participation of all key program staff in the International Programs Division, the regional directors, and other Council divisions. The effort to develop comprehensive regional and country programs might improve ECC's role.

8. ECC should not be subsumed under the OR program.

### **3.5 Program Accomplishments**

ECC has achieved a number of important accomplishments since the current agreement began in 1994, although many studies and activities are still underway and have not yet achieved expected results. The following highlights ECC accomplishments:

- ECC staff has played a crucial leadership role in working with public sector programs and providing technical assistance to ministries of health. ECC's involvement is helping to improve the quality of family planning services in countries such as Brazil, Kenya, Tanzania, and Zambia.
- Staff has provided technical assistance and training to medical and OB/GYN associations and has worked with women's groups in numerous countries including India and Senegal.
- ECC studies have increased understanding of the role and acceptability of the female condom; reasons for low acceptability of the diaphragm and also the effectiveness of using the diaphragm without spermicide; and acceptability of postabortion counseling and family planning services, and the need for providers to appreciate the benefits of those postabortion services. In Bolivia, a postabortion study led to the institutionalization of postabortion services in two public sector hospitals, and plans are underway to expand such services in other hospitals. In Brazil, an ECC study has increased understanding about adolescent knowledge, attitudes, and practices regarding sexuality, reproduction, and contraception.
- ECC has helped broaden contraceptive choice by facilitating product approval and registration of NORPLANT® in over a dozen countries, primarily in Africa.
- ECC staff has been an active and important player in USAID's MAQ initiative, especially in the Western, Eastern, and Southern Africa regions. Members of the ECC staff participate in three of the four MAQ subgroups, those on technical guidance and competence; client-provider interaction; and policy, advocacy, communication, and education. The ECC staff has the potential to do much more in this area. Staff members have also provided technical assistance to USAID and UNFPA country missions.

A major accomplishment has been ECC's work with the WHO Task Force on Research on the Introduction and Transfer of Technologies for Fertility Regulation in several countries—Brazil, Bolivia, Burkina Faso, Ethiopia, and Zambia. ECC has been a key contributor to the implementation and refinement of this strategic approach to contraceptive introduction.



The contraceptive needs assessment that was carried out in Zambia by host-country, WHO, and ECC staff had numerous important results including the following: (1) an expanded level of technical and financial support for research in reproductive health; (2) an influence on the procurement of three new additions to Zambia's public sector contraceptive mix (Depo-Provera, NeoSampoon, and PC4<sup>3</sup>); (3) the phasing out of 50ug estrogen-containing oral contraceptives from the public sector's method mix; (4) a contribution to the development of revised, user-friendly guidelines for family planning services; and (5) the provision of the MOH with a framework for research in contraceptive introduction. The results of this assessment continue to contribute to improved services in Zambia.

Many accomplishments have been the result of ECC's collaboration with other CAs and other donors, such as developing and revising guidelines for RH service delivery with JHPIEGO in Kenya and with Population Communications Services project (PCS) in Zambia (PCS paid for the publication of the MOH policy, strategy, and guidelines volume); developing intervention studies with CARE to improve contraceptive choice in Zambia; and supporting a broad needs assessment in reproductive health funded by UNFPA in Burkina Faso.

ECC staff have provided medical technical expertise to OR projects, in Zambia, for example, with the reintroduction of Depo-Provera and the introduction of emergency contraception.

ECC's success in developing collaborations within the Council, with host-country institutions, and with other donors has been a major accomplishment. Such collaboration has occurred because it was programmatically important and necessary because of limited ECC staff.

### **3.6 Dissemination**

ECC staff have carried out dissemination activities through participation in congresses, seminars, and workshops; through training sessions such as contraceptive technology updates; and through publications. The audiences for these dissemination activities range from senior policy officials and program administrators, medical professionals, and service providers, to women's groups. A review of the in-house projects and subawards shows that virtually every ECC-sponsored endeavor includes some dissemination work. Examples include the following:

- A national dissemination workshop held in June 1997 in Lusaka, Zambia, to launch the national family planning guidelines and standards.
- Presentations on results of the NORPLANT<sup>®</sup> expansion in Mexico at a regional Latin American association on human reproduction, preliminary results of the adolescent knowledge, attitudes, and practices (KAP) study in Brazil, and postabortion family planning in Bolivia.

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<sup>3</sup> A special product for emergency contraception.

- A dissemination workshop on the results of an MOH study of nurses providing NORPLANT® for the Nursing Council of Kenya, directors of family planning programs, and those responsible for on-the-job training.
- Publication of an article by Juan Diaz, et. al., in *Contraception* on bleeding complaints associated with NORPLANT® use, and plans to publish an article on the acceptability of the female condom in Brazil in the journal of the Brazilian Federation of Societies of Obstetrics and Gynecology.
- A planned dissemination workshop to present the results of a study of female condoms in Senegal.
- A national dissemination workshop on the needs assessment in Burkina Faso (supported by UNFPA).
- A workshop for OB/GYN specialists, paramedical and social workers, and nongovernmental organization (NGO) and governmental officials on injectable contraceptives with the Bhavnagar OB/GYN Society and Medical College in India.

ECC activities are also reported from time to time in "Population Briefs," a quarterly research newsletter of the Population Council. ECC's emphasis on dissemination is congratulated.

ECC has no specific requirement to disseminate the results of its program activities or findings more widely, and currently does not have the staff resources to do so. One added constraint is that some field reports and articles are written by staff for whom English is not a native language. To disseminate those documents, time and effort would be required in translation and editing.

ECC staff at headquarters and in the field would like to do more to disseminate the results of the program's work. For example, ECC staff in Brazil has been proactive in disseminating Shelton's "Contraceptive Pearls." ECC staff in other regions would see a role for themselves in such dissemination work if they had more time or staff. In the course of this evaluation, the team was informed about numerous topics that could be addressed by additional ECC dissemination activities. Examples of such topics are as follows:

- Current status of NORPLANT® use including when the Levonorgestrel 2-rod Implant System might become available and when, if, and how the 2-rod system would replace NORPLANT®.<sup>4</sup> Also, information on whether the approved length of NORPLANT® use will be extended is needed by other CAs for their program planning.

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<sup>4</sup> "Decisions for NORPLANT® Programs," *Population Report* was published in November 1992. This publication provided a useful, comprehensive summary, but much more experience has been gained (as well as new developments) in the technology since 1992.

- Current experiences with the female condom.
- Current experiences with emergency contraception. ECC staff in the Africa region see a need for a regional workshop on this topic. (It is possible that the Global Consortium on Emergency Contraception is planning such an activity.)

## Recommendation

9. ECC should be encouraged (1) to develop a more systematic dissemination plan, and to hire staff or a consultant to develop such a plan; (2) to identify topics or issues that should be addressed through a comprehensive or coordinated effort; and (3) to determine the most appropriate vehicles or channels for this dissemination. The topic of dissemination should be among the topics for discussion at all upcoming ECC semiannual meetings. Also, given that numerous CAs are already involved in research on some of the contraceptive technologies, such dissemination work should draw on the combine experiences of the CA community.<sup>5</sup>

## 3.7 Impact of Program Activities

Although ECC's various accomplishments have been described in Section 3.5, assessing the impact of ECC program activities is another issue. Through the initiative of the IPD director for policy and regional programs, impact studies are being developed and carried out in close collaboration with ECC staff in two countries: Senegal and Zambia. In Senegal, the study is entitled "An Experimental Study of the Impact of Improved Quality of Service on Continuity of Family Planning Use." It is being implemented by the National Family Planning Program of the Ministry of Health and Social Action. The study is cofunded by the Africa OR/TA project, ECC, and the Rockefeller Foundation. In Zambia, two impact studies are being implemented. One of the studies referred to as the Lusaka impact study, which is being implemented by the Central Statistics Office, is looking at contraceptive use dynamics after the introduction of NORPLANT<sup>®</sup> and the reintroduction of Depo-Provera. The other, "A Study to Enhance Contraceptive Choice and Improve the Quality of Family Planning Services in Zambia," is being carried out in a rural area of the Ndolo region where CARE International has been helping to implement an OR intervention. The study is truly collaborative, involving the MOH, CARE, WHO, the Population Council, and the Zambian Family Planning Association.

These impact studies are a very important new area of program activity. They provide an example of good interdivisional collaboration and have been carried out with partial funding from Rockefeller (part of a four-country impact study), ECC, and Africa OR/TA. These studies are still in progress, and their findings have yet to be determined. This impact research is vital. ECC has

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<sup>5</sup> One vehicle for such dissemination could be *Outlook*, a publication of the Program for Appropriate Technology in Health (PATH).

neither sufficient staff nor resources to enable it to carry out a comprehensive program to assess the impact of its interventions generally.

## **Recommendation**

10. The impact research that has been initiated by IPD's director of policy and regional programs should be an integral part of ECC's strategic approach for country-based work. Although that model appears very useful, ECC should also consider reviewing the experience of the USAID-funded EVALUATION project for additional ways to assess impact.

## **3.8 Collaboration and Coordination**

Many successful examples of ECC collaboration have been cited in the preceding sections of this evaluation. Additional examples and issues regarding collaboration and coordination follow. Other aspects of intra-agency cooperation are discussed in Section 5.2.

### **3.8.1 ECC and CBR**

ECC staff members have attended the ICCR semiannual meetings whenever possible to keep abreast of new developments in CBR. For example, ECC's annual meeting in November 1997 was scheduled to coincide with the ICCR meeting. With the change of leadership at CBR, communication between CBR and ECC is clearly improved. However, the nature of the interchange between CBR and ECC has been primarily in the form of information from CBR to ECC, rather than a true collaboration.

The Council states that it seeks to develop "methods that are safe, effective, easy to use, and affordable." The question that this evaluation team poses to the Council is, "For whom?" ECC has not been involved in the planning and oversight of Clinical Phase II programs. A Clinical Phase II program is comprised of all of the Clinical Phase II trials conducted for a particular product. Clinical Phase II programs address issues of safety and indications of efficacy. It is at this crucial phase that changes in factors such as the formulation, the level of service delivery at which the product can be offered, and the profile of clients that are candidates for use can be made. Once products have reached Clinical Phase III trials, it is not prudent or feasible to make further changes in the aforementioned parameters.

The Council's Phase II clinical programs have been conducted in developed countries and in model settings in developing countries. Therefore, safety and indications of benefit are established for populations in those somewhat idealized settings. Although it is easier to do Clinical Phase II programs in such settings, that strategy does not adequately determine the feasibility of use in truly low-resource settings, nor does that approach necessarily address various pertinent cultural

issues in possible target client populations that may affect product acceptability. Clinical Phase II programs can be conducted in any setting if good clinical practices (GCP) are followed. Such guidelines include formation of an ethical review board, documentation of essential elements of informed consent, written protocol with primary objectives established, standardized surveillance, standardized measurements, and government regulatory approval. Admittedly, conducting Clinical Phase II programs in low-resource settings and among special target populations may be more difficult. However, only by doing so can the Council's product development be relevant for the underserved populations who the Council and USAID are mandated to serve.

Vaginal ring contraceptives provide an instructive example. In the populations being attended through model clinics, it might be relatively easy to educate women to remove the rings for one week of each month. On that regimen, there might be high acceptability of the rings. In contrast, it might be determined that the regimen was not practical for illiterate women in rural settings, and another regimen might need to be explored. Perhaps the women should be instructed to take the rings out for a specified number of days only when spontaneous breakthrough bleeding occurs. During Phase III programs, efficacy for both regimens could then be evaluated.

ECC's knowledge of and experience with various service settings and special populations throughout the world provides the Council with unique insights to design relevant Phase II programs. ECC field staff (medical associates) have expressed a keen interest in such work.

## **Recommendation**

11. ECC should be integrally involved in Clinical Phase II programs to ensure that the products developed are relevant for underserved population in developing countries. This would involve addressing issues of acceptability, access, and indications of benefits in low-resource settings and among special target populations (see Section 3.8.1). USAID should be willing to fund the costs of this additional involvement since it is unrealistic to expect commercial partners to fully fund this part of the Clinical Phase II program.

### **3.8.2 ECC and IPD**

The most common collaborative efforts within the IPD have occurred between ECC and OR. Several such examples have already been cited. Good collaboration has occurred in spite of obstacles. An example of a constraint to collaboration is the following: ECC and OR in-country staff developed a joint proposal and obtained a commitment of outside support from UNFPA, only to be turned down by the OR regional project director because of limited OR staff time.

Although informal links between ECC and RH staff are good, there are examples of overlap in the work of these two programs, as described in Section 3.2, that complicate possible collaboration. ECC field staff reported that they used to attend the RH annual meeting (no meeting has been

held yet in 1998), and that it was helpful. Field staff should be encouraged to attend those meetings.

The GFD program seeks to bring gender concerns into all of IPD's other activities. Given ECC's focus on client perspective and user needs, these two programs share common interests. These links have not yet been translated into formal collaboration.

Given the newness of the HORIZONS project, that project's collaboration with other IPD programs cannot yet be assessed. However, ECC staff, especially in Kenya and Senegal, expressed an interest in exploring collaborative activities.

### **Team Comment**

The vertical nature of the programs within IPD has at times prevented collaboration and inhibits good coordination. One cause of this verticality is the nature of their funding.

### **Recommendation**

12. As the IPD develops its strategic plan, one key component should involve fostering transparent exchanges and collaborative efforts among IP programs. The field staff of ECC, OR, and RH need to be a part of this planning process. Also, perhaps a certain percent of uncommitted staff time and budget could be set aside within each program for future, undefined collaborative opportunities.

#### **3.8.3 ECC and Other Cooperating Agencies in Population**

Numerous examples exist of ECC's collaboration with other CAs. These include the following:

- A three-country study of new schemes for diaphragm use with funding from three programs: ECC, FHI, and WHO. The combined study was deemed necessary in order to have enough cases of diaphragm use; however, the study has been complicated by having three funding agencies and three countries. An added complication in Colombia—where the country study was funded by ECC—was that USAID assistance was terminated for a time because of U.S. legislative restrictions on funding to that country.
- Both AVSC and ECC have conducted contraceptive technology update workshops, and in some host-country settings (e.g., Kenya) these CTUs have been collaborative activities drawing on the particular strengths of the local CA staff. Typically, the Council's CTUs have been narrowly tailored workshops designed to help high-level policymakers and program administrators develop new or revised guidelines for a particular contraceptive method. AVSC's workshops, which have

focused on service providers, are more generic, broader in scope, and cover all methods.

- JHPIEGO and ECC have provided technical assistance for the development or refinement of family planning service guidelines and have worked together in some countries such as Kenya, Senegal, and Zambia toward this end. ECC's local presence in the region has been particularly useful in those joint endeavors. In contrast to ECC's approach, JHPIEGO's assistance in reviewing and revising guidelines is typically part of its more general involvement in the overall training process, so there has not been duplication of effort. In the case of Senegal, JHPIEGO took the lead in helping the MOH revise the service guidelines. JHPIEGO has suggested that a useful area for monitoring and evaluation would be to develop a module for the Situation Analysis (SA) to assess provider use of the new guidelines and to see what difference the new guidelines have made in improving quality of care.

Some CAs in population have stated that they are not clear on ECC's role within the IPD or at the Council. Thus, they have been unsure about how to collaborate with ECC. If collaboration is part of the Council's or ECC's plan at least at the headquarters' level, it is not well advertised.

Problems have occasionally arisen between CAs. One such example involved a request to ECC to facilitate the introduction or expansion of NORPLANT® in a given country. The local ECC staff judged that such a course of action was not well advised given constraints in the service delivery system. USAID then turned to another CA to carry out the request from the host-country MOH. Despite such occasional situations, ECC collaboration with other CAs has been good. The problem reflects the larger issue of appropriate introduction of contraceptive methods that ECC is trying to address and suggests that USAID mission staff need to better understand the issue of appropriate contraceptive introduction (see Section 6).

## **Recommendations**

13. The outcome of the mission and strategic planning exercise (Recommendation 7) should be communicated to potential collaborators among the CAs to improve future collaborative efforts.
14. As a follow-up to its technical assistance in revising service guidelines, ECC staff should collaborate with the new MEASURE project (assuming that Macro International awards a subcontract to the Council, such collaboration should be relatively easy) to develop a module for the Situational Analysis that can be used to monitor and evaluate the use of new guidelines. Furthermore, greater collaboration between ECC and JHPIEGO in the field might also ensure that efforts to revise service delivery guidelines are routinely related to a country's training programs.

### 3.8.4 ECC and Other Donors

The 1993 evaluation of the contraceptive introduction program noted that the involvement of other donors, primarily UNFPA and the World Bank, had been a crucial element. Under the current agreement, ECC has again collaborated with other donors. Both WHO and UNFPA have provided funding for some of the in-country work that has been implemented by ECC or jointly by ECC and WHO. Just as USAID has decentralized its funding mechanism for in-country work, so has UNFPA. This decentralization has meant less flexibility and more work for ECC field staff in approaching UNFPA country representatives and obtaining financial support for proposed ECC activities. Nevertheless, ECC field staff in West Africa have succeeded in obtaining such support (in Benin, Burkina Faso, and Gambia), which has been critical to fund ECC and other population-related activities in countries where USAID is no longer present.

Population Council staff, especially those in the ECC program, have worked hand-in-hand with the WHO Task Force on Research on the Introduction and Transfer of Technologies for Fertility Regulation. That collaboration has been especially fruitful both in terms of developing a conceptual framework for a more strategic or systems approach to contraceptive introduction (Spicehandler and Simmons, 1994), and in testing the three-stage framework. WHO and ECC staff members have worked together in carrying out Stage I needs assessments in Bolivia, Brazil, Chile, Burkina Faso, Ethiopia, Zambia, and Myanmar (with the assistance of a Population Council clinician who is not considered part of ECC's staff) (Simmons, et. al., 1997).<sup>6</sup> Typically, WHO has funded the needs assessment and ECC has provided staff time to assist with implementation. With the Zambia needs assessment, the Council staff member (who is supported by the Africa OR/TA contract as well as by ECC) devoted considerable time to this exercise.

ECC's experience in Zambia, which is considered by all accounts to have been very productive, was time-consuming and required a high level of commitment from the Government of Zambia, as well as the willingness of donors to fund different follow-up activities to ensure that the recommendations made in the needs assessment could be implemented. In contrast, the experience in Burkina Faso was more complex because of the broader nature of the assessment (reproductive health rather than contraceptive introduction), the absence of a USAID presence to help fund recommended follow-up activities, the more limited ECC staff time in shepherding the process, and insufficient local Council staff to develop follow-up interventions. The experience in Burkina Faso suggests that Stage I of the approach helps to develop a common understanding of the existing situation and problems, but it does not necessarily identify new problems and is no guarantee for comprehensive follow-up to the recommendations.

In addition to the Stage I needs assessments, ECC staff have helped to develop several follow-on activities that can be considered Stage II under the WHO rubric. In Burkina Faso, a family planning unit has been set up in the national hospital center—Centre Hospitalier National—with funding from UNFPA, which is the site for postabortion services and an OR study. The MOH is

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<sup>6</sup> Other needs assessments have been conducted in South Africa and Vietnam.



apparently interested in doing other Stage II interventions, but it is not clear who would fund those interventions or who would have the time to develop them. In Zambia, the Stage II interventions involve reintroducing Depo-Provera—a method that had lost popularity because of negative publicity in a neighboring country—while improving the provision of the whole range of methods in clinics in Lusaka and rural health centers in Ndolo, working through CARE as the local coordinating agency. The impact studies described in Section 3.7 could be considered the final part of Stage II prior to system-wide scaling up of the interventions in Zambia. In both Bolivia and Brazil, ECC staff are working with the MOH (and NGOs in Bolivia) to carry out Stage II interventions.

As for future WHO and ECC collaboration, WHO has asked a Council staff member, who has participated in Stage I needs assessments in Burkina, Ethiopia, and Zambia, to develop a manual on how to conduct a needs assessment. Such a manual will be very useful in laying out not only the steps involved in implementing this approach, but also the caveats, because the framework will not be useful in all settings and situations. ECC staff also anticipate that WHO may recommend expanding this strategic approach into several additional countries. At this time, ECC may not have sufficient staff to help implement this labor-intensive process in additional countries.

### **Team Comment**

ECC has both contributed to and benefited from the collaborative work with the WHO Task Force on Contraceptive Introduction. The strategic approach is an important advancement in the conceptualization of contraceptive technology. Beyond the Stage I needs assessment, successful follow-up or implementation of the recommendations may require additional resources. Joint follow-up with the OR program in designing these interventions—as occurred in Zambia—is very important.

The team congratulates ECC staff for working with UNFPA, particularly in West Africa, and for obtaining support for various program activities.

### **Recommendation**

15. ECC staff should continue to collaborate with WHO in implementing this strategic approach to contraceptive introduction, but should be very careful not to become overextended by taking on more countries than can reasonably be managed given existing staff constraints. If WHO sees ECC as the principal implementing arm for this approach, then WHO should consider providing core support to ECC if feasible. The Council should also pursue this possibility.
16. The ECC program at the Council, while benefiting from the collaboration with WHO, should continue to have a broader scope that encompasses issues related to the WHO Task Force. ECC clearly has other important program components, including the more traditional approach to contraceptive introduction where it is

deemed advisable, advancement of the MAQ initiative, and other initiatives that concern social and cultural factors affecting contraceptive choice.

## **4. OTHER POPULATION COUNCIL PROGRAMS UNDER THE COOPERATIVE AGREEMENT**

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The cooperative agreement has provided funding for activities and research that fall under the IPD and for research carried out by PRD staff, in addition to support for the Contraceptive Development and Expanding Contraceptive Choice programs. Under the previous cooperative agreement, support for such work under the IPD was described as family planning program research activities. In the Council's current agreement, this work is called family planning and related health services. Support for PRD studies was initiated under the current agreement.

### **4.1 Family Planning and Related Health Services**

Three types of activities and research have been funded under this category: (1) those activities that concern reproductive health, (2) the Experimental Family Planning Studies in Rural African Settings (primarily the Navrongo project), and (3) "other" assistance that USAID headquarters and field missions sought from the Council. The evaluation team was not asked to evaluate this part of the cooperative agreement. What follows is a brief description of what has been supported. The team's comments and recommendations on this work appear at the end of Chapter 4.

#### **4.1.1 Reproductive Health**

In reproductive health, some funding has been given to the Council's Robert H. Ebert Program on Critical Issues in Reproductive Health. The five-year proposal to USAID describes five key issues that could be supported in reproductive health:

- Improving the quality of care in reproductive health and family planning services;
- Understanding the causes of unwanted pregnancy and managing the consequences of unsafe abortion;
- Identifying ways to incorporate STDs and AIDS prevention and care into more comprehensive reproductive health services for women;
- Re-examining postpartum strategies for mother and baby; and
- Improving the safety of pregnancy, labor, and delivery.

Support for work in this area has, by and large, funded the participation of the RH program staff in meetings and workshops on the integration of family planning and reproductive health services. As described in the "1996-97 Annual Progress Report," several staff members have made

presentations, developed collaborative networks, and generally promoted the integration of family planning and health services.

#### **4.2 The Navrongo Community Health and Family Planning Project**

The Navrongo project is listed under the heading Experimental Family Planning Studies in Rural African Settings and covers a range of research studies being carried out in Ghana. The Navrongo Health Research Centre has been developed as an operations research field station in northern Ghana, funded largely through Africa Operations Research and Technical Assistance (OR/TA) Project II. The cooperative agreement has supported a large part of the time of the Council's senior advisor to the Navrongo project, who has had responsibility for technical and research backstopping.

The Navrongo project was designed to identify feasible means of mobilizing the cultural resources of a traditional African society to foster reproductive change. It tests the relative impact of alternative approaches to developing accessible family planning and other primary health care services. As research findings have emerged, village participants have been involved in dissemination workshops in Accra for senior policymakers and for journalists. On the global level, the project addresses questions about the demographic impact of family planning services in settings where demand is constrained. The Navrongo Centre team has given technical assistance to groups in South Africa, Gambia, Tanzania, and Mali. In addition to USAID funds, other sources of funding for the experiment include the Rockefeller Foundation for the surveillance system, the Mellon Foundation for Ghanaian fellows, the Finnish Development Agency (FINNIDA) for consultants, and the University of Michigan for fellows.

The Navrongo project was reviewed during the evaluation of the Africa OR/TA project (Adamchak, et. al., February 1988). The Council and USAID decided that since the Africa regional OR project is ending, continued support for this project should be entirely under the cooperative agreement.

#### **4.3 Other**

This third category of Council programs covers support through "add-ons" from USAID, both from Washington and the missions, for the Population Council's technical assistance to family planning and reproductive health programs; it is essentially a funding mechanism with good flexibility. Here again, the evaluation team was not asked to evaluate those activities. Referred to as "in-house projects," they include the following:

- Integration of STD and HIV/AIDS Activities into the Family Planning and Reproductive Health program (1995-1998), with funding from USAID's Africa

Bureau and under the auspices of the Africa OR/TA project. Studies have been carried out or are under development in Botswana, Kenya, Uganda, and Zimbabwe.

- Strengthening Population Policy and Research in Bangladesh with USAID/Bangladesh funding for a two-year project (1995-1997) that included two studies: (1) Opportunities for integration of RTI/STD services in the Maternal Child Health and Family Planning program (MCH-FP); and (2) strengthening of STD services for men, and the publication of a series of brief papers entitled *Policy Dialogue* as a way to influence health and population policy.
- Population Support to the MCH-FP Rural Extension Project, the International Centre for Diarrheal Disease Research (ICDDR)/Bangladesh with USAID/Bangladesh funding for a two-year project (1995-1997) of applied research, dissemination, and technical assistance to improve the national family planning and maternal and child health programs. Several interventions were field-tested, including cluster visitation as an alternative to community-based distribution, satellite clinics combined with the Expanded Program on Immunization (EPI), comprehensive essential obstetric care, and an essential services package. Several major research monographs were also published.

#### **4.4 Population Policy Research**

Under the cooperative agreement, USAID has begun to support for the first time research carried out by the Policy Research Division. The one program area that has received partial support so far under the agreement is Understanding and Meeting the Needs of Adolescents. This program is concerned with the determinants of adolescent reproductive behavior, namely early marriage, sexual activity, and childbearing. One research study on schooling and the experience of adolescence in Kenya has contributed to public discussions of gender equity in the educational system, retention of girls in school, family life education in schools, and pregnancy among school girls. The Ministry of Education and numerous donors have requested that interventions based on this research be carried out. As of this date, no specific interventions have been developed following an August 1997 dissemination workshop held in Nairobi. However, PRD staff is planning to discuss possible follow-up interventions with the Council's regional director for Africa later this spring. Furthermore, the British Department for International Development (DFID) is considering funding a new gender initiative at the MOE that may involve training teachers. In addition to the project in Kenya, USAID-funded projects in Bangladesh, Egypt, and South Africa are beginning.

Staff of PRD also discussed with the evaluation team two areas of research that are currently being pursued and are being proposed for USAID support. The first area of research addresses the three components of population growth and their corresponding policy options. First is

unwanted fertility and unmet need for contraception and abortion. Strengthening family planning and reproductive health programs are the policy options. Second is high desired family size with a policy option that emphasizes human development and, in particular, education, gender equality, and child health. Third is the momentum of population growth. Here, the policy option is to encourage delays in childbearing, for example, by addressing schooling, employment, and recreation for adolescent girls as alternatives to early marriage and childbearing. The analysis of components of growth has been carried out for India, Kenya, and the Philippines. In Kenya, the government's new national plan, developed in 1997, addresses the issues raised in the analysis and is especially concerned with unmet need, adolescents, and gender issues. A further analysis based on this model has been carried out by a Kenyan demographer. This analysis, "Fertility Decline in the Kenya Transition: An Assessment of Underlying Factors," will be presented to the Government of Kenya this spring under the auspices of the African Population Policy Center, which is housed in the Council's regional office in Nairobi and is supported by the Rockefeller Foundation.

A second area of research involves investigating the diffusion model and the adoption of modern contraception. Panel surveys are planned in Ghana to examine how individuals influence each other's fertility behavior and how both negative and positive messages about family planning are diffused.

The principal objective of PRD's research is to generate new knowledge to improve population policies and programs, and the division's research is often field-based and conducted in partnership with colleagues from developing countries. Although the PRD has collaborated in a major piece of intervention research with the Navrongo Health Research Centre in Ghana, its research program does not typically test or carry out interventions. In general, intervention research is carried out by the IPD. At present, no mechanism exists within the Council to provide the bridge between PRD research and programs in developing countries in the manner that ECC has done for CBR in terms of introducing NORPLANT® and IUDs.

The process for garnering USAID funding for PRD research has been informal, and the level of support has been quite limited. Currently, proposals are reviewed by the USAID technical advisor in the Research Division in consultation with staff of the Policy and Evaluation Division (P&E), whose mandate is in fact closer to the PRD's work. Those proposals of interest to USAID receive funding. Funds from other donors are also sought by PRD to fund those and related research activities.

The team discussed the desirability of creating a working group involving outside expertise to help guide the Council's social science and field research programs. Such a group could facilitate communication within the Council and with other agencies and provide more national and international visibility to the work of both the IPD and PRD. Several senior staff at the Council found this idea attractive and worth exploring.

## **Team Comments**

The team finds the research supported under the cooperative agreement very exciting. USAID funds have been well leveraged. The agreement has provided a flexible, useful mechanism for USAID, both in Washington and in missions, to invest in new and ongoing Council work. The PRD's research seems to fall more within the domain of USAID's P&E Division than within the Research Division. However, P&E-funded research is now commissioned and directed, rather than arising in response to funding requests such as those of PRD.

It is not clear why more work was not funded under the area of reproductive health, although it may be that the vertical nature of the IPD (discussed in Section 3.8.2) has been a contributing factor.

The team fully supports USAID and the Council's decision to fund support of the Navrongo project through the cooperative agreement. This project represents a unique, combined research and services program in Africa, and the Council's continued technical and financial support is deemed essential.

## **Recommendation**

17. The team finds the research supported under the agreement to be very interesting and worth continued support at a higher level than before. In addition, USAID should consider moving the review and funding of the PRD research projects to the P&E Division, unless such a move would jeopardize that source of funding under the cooperative agreement, or unless that move would restrict the investigators of the PRD because of too much USAID direction. Thus, USAID is encouraged to invest more in the division's program, which is on the cutting edge of social science research and analysis.
18. A mechanism should be created within the Council to develop and carry out appropriate intervention studies once the PRD's research has reached a point where potential programmatic implications are identified. Those activities should be supported with USAID funding.
19. The Council should consider establishing a working group involving outside expertise to help guide its social science and field research programs in both IPD and PRD. That working group would also further collaboration with other organizations. A working group could also play a role in looking at the array of programs within the IPD and how they might be configured.





## **5. ORGANIZATIONAL MANAGEMENT, PERSONNEL, FINANCES, AND FACILITIES**

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### **5.1 General Administration of the CA**

The cooperative agreement is a funding mechanism for programs in the Council's three divisions: CBR, IPD, and PRD. Each division is responsible for administering its own programs. The vice president for corporate affairs oversees seven departments: Legal, Personnel/Office Services, Information Systems, Finance, Grants and Contracts, Publications, and Public Information. The Office of Grants and Contracts coordinates the submission of annual reports, workplans, portfolio reviews, and country expenditure reports for the cooperative agreement. This coordination involves collecting information and material from the various divisions, editing text, verifying the data, and placing it within USAID's Strategic Framework. This office also provides the divisions' staffs with interpretations of agreement regulations; prepares and submits requests for approval for travel, consultants, and subawards; and responds to ad hoc requests for information (financial and programmatic) from USAID. In the Legal Department, the general counsel is a generalist and not specialized in intellectual property rights.

The cooperative agreement supports administrative staff in both the CBR and IPD (full-time for ECC staff) that help administer the work of the divisions. Organizational charts for the three program divisions and for the Office of Corporate Affairs are presented in Appendix H. USAID raised numerous other administrative questions in preparing for this evaluation. The Council's response to these questions are in Appendix G. The team has reviewed these responses and discussed them as needed in the body of this report.

USAID staff commented that the management of the cooperative agreement is more difficult than it might be because many different Council staff have to be contacted when issues are raised. This problem is made concrete by reference to the cover letter for Appendix J, the Annual Workplan, in which six different Council staff are identified as contacts if USAID staff "have any questions or require additional information." The issue of the lack of a primary contact person for interaction with USAID was raised during discussions with Council staff.

### **Team Comments**

The team believes that administration has improved since the last evaluation. It appears that issues raised at the last evaluation concerning standardization of computers were largely resolved, and that a new, satisfactory financial accounting system has been put in place.

## **Recommendations**

20. The Council should identify one highly ranked person to interact with the USAID technical advisor. This individual should handle both administrative and program issues.
21. The Council should consider special training for the legal counsel in intellectual property rights.

### **5.2 Coordination among Council Programs**

A Strategy Advisory Group (SAG) was established at the Council about two years ago and is chaired by the vice president for corporate affairs. The SAG is composed of all staff members above a certain salary grade and meets for about three hours approximately five times a year including semiannual meetings with the regional field directors. All those interviewed agreed that the SAG provides an excellent opportunity to facilitate intra-agency cooperation and serves as a forum for discussion of substantive scientific and administrative issues. It has been very useful in bringing together three very different cultures among the Council's staff: biomedical researchers, public health specialists, and social scientists (including demographers).

The team was told that in the recent past there was conflict between the CBR and the IPD. Staff reported that they had been taken off certain projects when it was discovered that they were collaborating with staff from other divisions. It appears that this is no longer the case. Nearly everyone interviewed declared that the relationships among divisions, particularly between the CBR and the IPD, have improved. (See Section 3.8 and 4.2 for more discussion on collaboration and coordination among the divisions.)

#### **Team Comment**

The team commends the Council for its efforts in improving intra-agency cooperation and recommends elsewhere in this report ways to enhance such collaboration.

### **5.3 Personnel**

The evaluation team focused its review of personnel issues on the composition and staffing of only two programs: contraceptive development and ECC.

### 5.3.1 Contraceptive Development

The organization of the CBR is displayed in Appendix H. Seventeen scientists on the staff of the CBR were interviewed. All staff except Dr. Barfield, who is now the Center's financial manager, and Dr. Gunsalas, who is now the Center's computer specialist, work in the contraceptive development unit. Only 2 of the 14 individuals in the contraceptive development group are women; 13 have worked for the Council for 20 years or more. It is noted that the age structure and the gender distribution at CBR as a whole are fairly well balanced.

Most of the scientists interviewed said that they find the new leadership to be more open and collegial. Conflicts with other Council units apparently are no longer the serious problem they were in the past. Many staff expressed concern that the vice president is, of necessity, preoccupied with negotiations with industry and has less time than desirable to devote to day-to-day operations. Although several staff commented that the current vice president of CBR, Dr. Johansson, has been intellectually stimulating as a member of ICCR, a minority of staff said that the current leadership appears to be excessively preoccupied with cooperation with industry, thus reducing the intellectual stimulation that they claim was obtained previously. The team believes that once a director of contraceptive development is on board (as noted in Recommended 22), such stimulation will be greatly facilitated. Filling this position will also provide the vice president more time for collaboration with industry, which he has successfully undertaken.

Not unexpectedly, almost everyone claimed that additional staff is necessary. One staff member said that he had a vacant position to fill; another said that he had identified someone to recruit, but had been told that not enough funds were available to fill the position.<sup>7</sup>

There is an apparent lack of commonly held information among some of the staff. This indicates a need for better communication, in part through regular, substantive staff meetings. The vice president of CBR related that he is aware of those needs and intends to act on them.

### Recommendations

22. An established, respected scientist should be appointed director of the contraceptive development unit as soon as possible to provide more day-to-day direction and intellectual stimulation in the division since the current vice president of CBR does not have time to serve this need.

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<sup>7</sup> The Population Council states that there have been no instances in which a vacant position has not been advertised, and no single instance of a position not being filled due to lack of funds can be identified.

23. The CBR staff, though well motivated and skilled in their fields of interest, must be augmented. Furthermore, the highest priority should be given to recruiting women in the contraceptive development program.

### 5.3.2 Expanding Contraceptive Choice

The evaluation of the previous cooperative agreement (1988-1993) (Harper, et. al., 1993) recommended that the Council strengthen and increase ECC's staff at headquarters and in the field. To an extent, the Council has followed these recommendations, but with only moderate success. A senior social scientist was hired as program director of family planning with part-time responsibility for ECC. In August 1997, after two and one-half years on the job, the Council moved him to a new position as director of the HORIZONS project. (Although the former program director was instrumental in carrying out an important study under ECC on NORPLANT® removal in Indonesia and helped to design the ECC strategy for India, it does not appear that he had the time or interest to develop ECC.) In August 1997, the current deputy was promoted to ECC program director. Additional field staff were hired, including a social scientist based in Nairobi (available part-time to ECC activities in the entire Africa region) and a full-time social scientist and part-time medical expert both based in India, with responsibility for work only in that country. From time to time, consultants are hired to help with specific monitoring and implementing activities.

The current staff members of ECC are capable and productive, given the demands on their time and their limited numbers. As has been discussed in Section 3.4 on ECC planning, the content of ECC has largely been determined by the skills and time constraints of the staff. The current project director has an excellent understanding of the importance of an ECC emphasis within the Council programs and the special role that ECC can play in service delivery programs. She does not have the time (and in some areas, the expertise) to carry out all of the tasks required in her position, which among other responsibilities, include the following:

- Giving guidance and leadership to research projects that require strong social science research skills;
- Working within the Council to ensure that ECC is a vital part of the program that works consistently with other programs (such as RH, HORIZONS, OR, or PRD) in planning and implementing joint research and intervention activities; and
- Disseminating the results of ECC's work to as broad an audience as possible.

The field staff does what it can in the countries where it is charged and able to work. The role of the medical associates is important and is enhanced when they work in tandem with social scientists. At present, the limited time social scientists have is a constraint. On occasion,

consultants have been hired who can assist, but this has typically been to help implement a subproject (subaward) activity (e.g., in Senegal).

All of the current staff see greater potential for this program area within the Council, but they suffer from the program's relatively weak position within the organization. The team has identified several reasons for this weak status: (1) the ECC director, who is talented and imaginative, is nevertheless a mid-level professional within the IPD and as compared to some of the field staff; (2) the collaborative links among the most relevant Council programs and staff are informal and ad hoc; and perhaps most importantly, (3) the conceptual basis for the different programs (including how ECC fits) within the IPD, and necessarily involving work developed in the field, has not really been well developed.

Two minor issues of subproject management are related to personnel and are thus mentioned here. Evidence suggests that ECC staff both at headquarters and in the field do not have sufficient time to oversee subproject management and monitor subawards, such as the diaphragm study in Colombia. Further, there is evidence of occasional delays in reporting on ECC activities (USAID mission comments in Mexico and Kenya). ECC field staff must first send reports to headquarters for review and editing. These issues suggest that additional staff (consultants where feasible and useful) are needed to do the job better. In addition, perhaps arrangements should be made to brief USAID mission staff informally (via e-mail or in-person) when delays in getting the formal, written record are anticipated.

### **Team Comments**

The current composition and staffing of ECC is adequate for a relatively low-priority program and if the Council is content to live with the existing overlap and at times dysfunctional separations across the various programs within the IPD. The team is disinclined to recommend strengthening the ECC staffing without the Council determining its proper role within the overall International Program.

If the Council determines a critical role for ECC within the IPD or as a link across divisions, the structure and staff would necessarily be assessed and would, in all likelihood, require changes. The evaluation team considers the combined expertise of medical advisors and social scientists an essential ingredient. In addition, more complete staff coverage would be needed within each geographic region.

## **5.4 Finances**

The total amount of funds obligated to the Council for the first four years of the current cooperative agreement (fiscal year 1994 to 1998) is \$33.5 million (see Appendix M). This

compares to \$36.4 million for the previous agreement that covered 1988 to 1993.<sup>8</sup> On average, USAID has provided about \$600,000 more per year under the current agreement than in the previous one. Although the figures in Table 2 are approximate, they show that the distribution of these funds has shifted in some areas.

**Table 2**

**Distribution of USAID Support under the Cooperative Agreements by Program Area**

<b>Program Area</b>	<b>1988 to 1993* (%)</b>	<b>1994 to 1997 (%)</b>
Contraceptive development	42.1	35.9
Contraceptive introduction/ECC	15.0	18.3
FP/FP and related health services	12.2	12.3
Policy research	**	0.9
Other direct (audit)	0.1	0.5
Indirect	30.7	32.1
Total***	100.0	100.0
Total (in millions)	\$36.1	\$33.5

\* Includes expenses incurred through the extension of the previous cooperative agreement to the end of 1995.

\*\*Some support covered Council staff time for technical assistance to Matlab and later Navrongo.

\*\*\*Percentage totals may not add up to 100 percent because of rounding.

Support for biomedical research has declined by several percentage points or just over \$3 million. Support for ECC has increased by about \$700,000. Funding for family planning and health-related services—primarily as add-ons for assistance to Bangladesh, Navrongo, and STD/HIV/AIDS work in Africa—has remained relatively stable. Finally, support for policy research is still at a very low level, but it has increased from the level under the previous agreement.

The Council was asked to indicate what percentage of its overall funds comes from USAID and in turn what percentage comes from the cooperative agreement. For 1997, when the Council's total budget was \$50 million, USAID provided \$24.2 million or 48 percent. Funding in that year through the cooperative agreement was \$6.4 million, roughly one-quarter of all USAID support or almost 13 percent of the total Council budget. Remembering that the cooperative agreement is for programmatic support, that is, an investment in the Council's ongoing program, as opposed to

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<sup>8</sup> That amount includes some funds that were obligated in FY 1994 for the previous cooperative agreement.

purchasing a set of activities (as happens under other USAID contracts and agreements with the Council, such as operations research), this level of support seems quite appropriate.

The financial tables in Appendix N show the relative contribution of cooperative agreement funding to each of the Council's three divisions. Looking at just 1997, the cooperative agreement represented 42 percent of the direct costs of the contraceptive development program of CBR, 8.6 percent of IPD (or 4.7 percent if only ECC funding is considered), and 9.8 percent of PRD's budget (when support for both the adolescent research program and PRD staff time on the Navrongo Project are included).<sup>9</sup>

**Table 3**

**Comparison of Proposed Funding Levels, Actual Funding,  
and Expenditures by Program Area, 1994-1999**

<b>Program Area</b>	<b>Proposed Funding 5 Years</b>	<b>Actual Funding Years 1-4</b>	<b>Expenditures to October 1997</b>	<b>Spent Years 1-3* (%)</b>
Contraceptive development	21,762,066	12,052,036	6,100,378	68
ECC	8,864,980	6,126,975	2,935,041	56
FP and related health services	4,673,791	4,112,657	3,375,176	91
RH				
Navrongo	646,000	105,069	104,328	99
Add-ons	811,256	685,813	311,308	45
Bangladesh	3,163,190			
STD/HIV/AIDS in Africa		2,558,811	2,630,788	103
		762,964	328,752	67
Policy research	1,138,883	296,047	203,390	92
Other direct (audit)	200,000	168,503	5,795	5
Indirect	16,930,578	10,775,519	5,668,295	67
<b>Total</b>	<b>53,510,298</b>	<b>33,531,737</b>	<b>18,288,075</b>	<b>68</b>

\*Expenditures for years 1 to 3 as a percent of actual funding for years 1 to 3. The sum of actual funding for years 1 to 3 is not shown in this table, but appears in Appendix M.

Table 3 presents a comparison between what was presented in the Council's revised five-year proposal, dated March 31, 1994, and what has actually happened. Looking at actual funding for years one to four in comparison with proposed levels for these same four years—thus using only four-fifths of the five-year proposed budget shown in Table 3—funding for the entire cooperative

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<sup>9</sup> Assigning the costs of the Navrongo project is somewhat complicated. Since the project began as an OR project, it was part of the IPD. However, since the PC senior advisor on the project is part of the PRD staff, his time is listed among that Division's costs.

agreement is about 78 percent of what was expected. Since USAID funding levels are never guaranteed because they are subject to annual appropriations from the U.S. Congress, this level is reasonable. The two areas that had the lowest level of proposed funding (policy research and reproductive health) have very low levels of actual funding. The Council did not carry out as much work in these programs with USAID funding from the cooperative agreement as had been anticipated in the Council's proposal to USAID, because USAID reportedly did not give priority to those areas. The level of expenditure compared to actual funding is also shown in Table 3. For the cooperative agreement as a whole, nearly 70 percent of funds were spent for years one to three.

The majority of funding—86 percent—for the cooperative agreement came from core funds provided by the Office of Population. The remaining 14 percent came primarily from the USAID mission in Bangladesh, but also from field support in 12 other countries and USAID's Africa Bureau. Just over one-quarter—27 percent—of ECC funds came from field support, which is impressive given the amount of staff time that it takes to develop proposals for field-supported activities.

#### 5.4.1 Contraceptive Development

Funding from many donors is required to support all the different projects of the contraceptive development program. USAID has provided 42 percent of the contraceptive research and development budget for the years 1988 to 1997 (see Appendix N). The total amount of USAID support for the years 1994 to 1997 was approximately \$12 million, but through September 1997 only \$6 million had been expended (see Appendix M). Major underspending occurred in many categories. The reason for this underspending was not clear; however, it did not appear that lack of funds was constraining progress in method development.

#### Team Comments

The Council's contraceptive development activities appear to be adequately funded at the present time. It is anticipated, however, that given success with current programs, the need for additional funds will arise.

#### 5.4.2 Expanded Contraceptive Choice

Under the previous cooperative agreement (see Harper, et. al., 1993), the budget for the Contraceptive Introduction program was \$5.4 million. Other donors contributed about \$3.2 million from 1988 to 1992.<sup>10</sup> Under the current agreement, USAID has provided \$6.1 million to

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<sup>10</sup> Other donors included UNFPA, the International Development Research Centre (IDRC), the Packard Foundation, FINNIDA, World Bank, WHO, and the Rockefeller Foundation.



date. Another \$1.3 million, or about 18 percent of the ECC's overall funding, came from other donors, such as UNFPA, WHO, and the World Bank, as part of its project with the Government of Kenya. As shown in Table 3, the level of expenditure for ECC is 56 percent, considerably below the average for the overall agreement. This may be because of the more limited number of staff working on ECC who can develop and carry out program activities.

The team learned of one instance when the Council's financial management procedures placed an undue burden on regional Council staff to negotiate and, in turn, on a host government to report. The problem involved an activity that was funded by two Council programs—ECC's Cooperative Agreement and the Africa OR contract. The Council's staff at headquarters apparently required the MOH to report separately on the same activity because of the two sources of funds and USAID's requirement that these subawards be reported on separately. The team finds this procedure for financial accounting unduly complicated. A simpler formula could be applied at headquarters to assign costs to the different funding sources. Such an accounting change would require agreement from USAID, which presumably would be possible to obtain.

### **Team Comments**

Since the level of expenditures relative to funding for ECC under the cooperative agreement is not high, and considerably lower than the overall Council average, the Council should look at this issue to understand what is happening and determine if some constraints can be removed. ECC was quite successful in obtaining funds from USAID field missions, as well as from other donors. Assuming the ECC remains an important area for the IPD, the team encourages the Council to seek more non-USAID funding for core support to give the program greater flexibility to expand staffing and to work in additional countries.

Given the years of Council experience in working with local governments and institutions in many countries, the team is certain that the Council can find a simple way for local institutions to report expenditures when they are funded by more than one Council program, assuming that USAID's Office of Procurement permits such a solution.

## **5.5 Facilities**

The evaluation team decided that a review of the Council's facilities was needed only for the contraceptive development program; thus, this discussion concerns only the CBR. The basic science and contraceptive groups are housed mainly on separate floors of the Rockefeller Tower at Rockefeller University. The basic scientists are on the seventh floor, the contraceptive development group on the fifth floor, and some basic scientists and the administrative component on the sixth floor. Despite this propinquity, interaction between the groups may not be optimal. A recent NICHD site-visiting team, which recommended the renewal of the basic science Reproductive Physiology Center U54 award, also recommended that the laboratory facilities be upgraded and refurbished. The president of the Council stated that that was believed to be a major

priority and that about \$15 million would be required for a complete renewal of the labs, including expansion to the fourth floor. She said that an architect had been hired and plans were being developed. The Packard Foundation has been approached for the necessary funding.

At a meeting at the labs, it was explained that CBR is well along with plans and funding for moving the fifth-floor staff to the refurbished fourth floor. Details of the plans for reconstruction are displayed in Appendix I. Construction on the fourth floor is scheduled to begin in September 1998, and construction on the fifth floor is scheduled to begin in early 1999. The council plans to have three GLP rooms, with special provision for Dr. Phillips's work with viruses and other pathogens. It has not yet been decided whether a full four floors will be required for CBR operations, although that is an option. However, rental costs for space are high, having been raised recently from \$27 to \$60 per square foot. That increase was partly owed to a restructuring of the way the Council was surcharged for use of the Rockefeller University facilities, such as the library and animal facilities. Those surcharges no longer are applied but are built into the rent, which is now the same for all scientists using university facilities.

### **Team Comments**

The team is encouraged by the Council's plans to modernize its laboratory facilities. If the administration is successful in raising the full amount, the CBR will not only be able to provide adequate facilities for its current staff, but will also be able to attract young investigators who should be in a position to stimulate and expand the Council's biomedical research activities.

## **6. RELATIONSHIP WITH USAID**

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The Council's programmatic support from USAID continues to be managed by the Research Division of the Office of Population as it was under the previous cooperative agreement. The relationship between USAID and the Population Council, improved from the last evaluation, is on the whole quite good because of two factors: (1) the change of CBR leadership and (2) the continuity of the USAID staff person monitoring the cooperative agreement. The USAID technical advisor is a well-respected professional, who takes her role seriously and carries it out well. As discussed in Section 5.1, the USAID technical advisor has to deal with a range of staff at the Council because the cooperative agreement funds are used by three different divisions (see Recommendation 20).

Changes in the USAID environment over the life of the current agreement are presented in Section 1.3. With regard to these changes, the team was asked to look at the Council's response to USAID reengineering. The Council has adjusted to USAID's reengineering framework of strategic objectives and results both in its annual workplan and in its annual progress report. The staff in the Council's Office of Grants and Contracts have been most involved in revising the Council's reporting to USAID. The team finds the Council appropriately responsive (even though it did take somewhat longer than usual to prepare the annual report), but sees little positive impact on the type of work or its implementation as a consequence of reengineering. ECC field staff did state that the new reporting by results has helped them to better describe their technical assistance activities.

USAID/Washington sent a cable to USAID field missions asking for comments about the Council's work under the Programmatic Cooperative Agreement, and nine missions replied. Comments about ECC's work were almost uniformly positive. USAID/Brazil described ECC's work as "worth its weight in gold." USAID/Kenya reported that the Council had played a significant role in introducing NORPLANT<sup>®</sup>, a very popular method among Kenyan women, and increasing the number of available methods. The Council's collaborative work with both the MOH's Division of Primary Health Care and other CAs was also lauded. The USAID mission in Bangladesh commented favorably on the range of activities with which the Council assisted, and on the good communication between the Council and USAID, as well as between the Council and other CAs, NGOs, and donors in the country.

Several missions inquired about ECC's capabilities. USAID/Senegal asked whether ECC could assist with introducing emergency contraception. USAID/Madagascar is apparently unaware of the French-speaking staff (based in Senegal) associated with the program that it might draw on. USAID/Indonesia asked about the introduction of the Levonorgestrel 2-rod Implant System. USAID/Egypt, where the Council's OR project has been active, expressed interest in expanding method mix to include Depo-Provera and voluntary surgical contraception (VSC), because the current program is essentially a two-method program with most women using IUDs or pills.

A criticism offered by several missions was that communication from ECC to mission staff has often been weak. Meetings have not occurred regularly and reports have not always been timely. A remedy for this criticism is offered in Section 5.3.2.

ECC staff noted an important issue in working with USAID missions (See Section 3.8.2). The issue concerns requests for contraceptive introduction by USAID missions and presumably host-country ministries of health. Introduction of a particular method may not be appropriate in some settings. USAID mission staff need to be apprised of these constraints so that the best programmatic decisions are made instead of simply asking another CA to carry out the work.

### **Recommendation**

24. The USAID Research Division should talk to USAID mission staff about making appropriate decisions on contraceptive introduction, which would reinforce the Council's advice on such matters and ensure that the best programmatic decisions are made in different countries.

## **7. RECOMMENDATIONS FOR THE FUTURE**

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The team presents its recommendations in two parts: those that pertain to the remainder of the current agreement and those that concern a follow-on agreement for which the Population Council has proposed a Five-Year Strategic Plan: 1999-2004 (see Appendix K).

### **7.1 The Remainder of the Current Cooperative Agreement**

#### **7.1.1 Contraceptive Development**

A discussion of the present status of each contraceptive development project is provided in Section 2.5 and in the report on the April 1998 ICCR meeting in Appendix D. Therefore, that discussion will not be reiterated here. The plans outlined at the ICCR meeting continue the various projects under investigation through the end of the present cooperative agreement. No reason exists to change this strategy; even for projects that should not receive future USAID support, such as GnRH immuno-contraceptive, the present studies should be completed.

#### **Recommendation**

25. The studies proposed by CBR for the balance of this cooperative agreement should be continued.

#### **7.1.2 Expanding Contraceptive Choice**

Several of the recommendations on the ECC program (Recommendations 7, 8, and 12) concern its mission and role within the IPD. It is very important that the Council and especially the IPD conduct a careful review of the division's portfolio of programs to examine critically their conceptual bases, the interrelationships among programs, and whether some conceptual clarification and consolidation is warranted. At the very least, better planning and coordination would lead to more effective programming. In the previous evaluation, a similar call for more collaboration was made. To an extent, such collaboration occurred in several countries, but improving the effectiveness of the IPD programs is not just a matter of better collaboration. Many IPD programs have changed over time, often independent of one another. Thus, the time is appropriate to carry out such a division-wide review. Decisions on changing ECC's structure, staffing, and funding should await the outcome of this review.

Numerous specific recommendations have been made that should be addressed during the remaining life of the current agreement. These involve (1) more systematic dissemination of ECC results (Recommendation 9), including attention to particular topics such as the Levonorgestrel 2-rod Implant System, the female condom, and emergency contraception;

(2) definition of the Council's role in promoting and supporting NORPLANT® in developing countries; (3) work with the MEASURE project on assessing use of service delivery guidelines (Recommendation 13); (4) work with the HORIZONS project, particularly in the Africa region (Section 3.8.2); and (5) study of the problem of declined use of IUDs in Kenya (see Section 3.3).

Additional recommendations have bearing on both the current and follow-on agreements: The team considers impact research very important (Recommendation 10). ECC should be involved more in Clinical Phase II contraceptive development programs (Recommendation 11). ECC should continue to work closely with WHO without getting overextended, unless WHO is willing to provide core funding to the program (Recommendation 14).

### 7.1.3 Population Policy Research

The team fully supports USAID and the Council's decision to fund support of the Navrongo project through the cooperative agreement. Furthermore, the team recommends continued funding of PRD's endeavors at a higher level than before, and recommends that USAID consider moving the review and funding of PRD research projects to the Office of Population's P&E Division (Recommendation 17). The team also recommends that the Council create a mechanism within the organization, presumably in IPD, to facilitate the conduct of appropriate intervention studies, based on the PRD's research (Recommendation 18).

## 7.2 Review of the Strategic Plan for 1999-2004 and Recommendations for a Follow-on Cooperative Agreement

The team supports USAID's funding of a follow-on cooperative agreement with the Population Council. The Council's unique program of contraceptive development fulfills a critical need in the population field. Specific comments on the Council's Strategic Plan for 1999-2004 in contraceptive development follow in Section 7.2.1. The Council's proposed Strategic Plan for Expanding Contraceptive Choice provides a good basis for further developing this program. Specific comments on this component of the plan follow in Section 7.2.2. In Population Policy Research, the team reiterates its recommendation to continue funding, but at higher levels than before (see Recommendation 17 and Section 7.1.3).

The team does not see any merit to competing a new cooperative agreement. The Council's work in all three program areas—contraceptive development, expanding contraceptive choice, and population policy research—is sufficiently unique and draws on years of institutional capability and experience. Therefore, USAID should continue to contribute its financial support of the Population Council through a non-competitive, follow-on programmatic cooperative agreement.

## Recommendation

26. USAID should continue to contribute its financial support of the Population Council through a non-competitive, follow-on programmatic cooperative agreement. The Council's work in the three program areas of contraceptive development, expanding contraceptive choice, and population policy research is sufficiently unique and draws on years of institutional capability and experience. Therefore, the team sees no merit in competing a future cooperative agreement.

### 7.2.1 Contraceptive Development

#### Strategic Planning

In discussions with Dr. Johansson regarding strategic planning for the contraceptive development program, he indicated that most of the staff did not see the "big picture," and that, in reality, such planning arose from the ICCR meetings. He intends to involve more of the good young scientists in the basic research program as generators of new ideas. Involving those individuals will require greater collaboration and interaction between the basic and applied groups than has been apparent heretofore. A recent example was the work of one of the basic scientists on a male method, proceeding in ignorance of the fact that one of the applied group researchers had conducted studies on a related compound several years earlier. More frequent exchange of information could obviate this situation.

For the present, the leads to be pursued with high priority are male methods and transdermal preparations of Nestorone<sup>®</sup> and MENT<sup>™</sup>. The project intends to bring to a close activities on the single implant, Nestorone<sup>®</sup> alone and Nestorone<sup>®</sup> plus estradiol vaginal rings, and NORPLANT<sup>®</sup> and the LNg 2-rod Implant System. Given the above, concern was expressed by some staff members about the lack of new products in the pipeline.

## Recommendation

27. There should be greater interaction between the basic and applied groups. (See also Recommendation 1 under Section 2.2.)

#### Subdermal Implants for Women

**NORPLANT<sup>®</sup>**. The Council intends to seek regulatory approval for NORPLANT<sup>®</sup> as a seven-year device. Since the commercial partner for NORPLANT<sup>®</sup>, Wyeth-Ayerst, apparently is not interested in this venture, the Council may seek the necessary label change through its own new drug application (NDA) for this product. The cost—approximately \$150,000—will require USAID funding.

**Levonorgestrel 2-rod Implant System.** The Council intends to submit an application to amend the labeling from a three-year to a five-year device. As with the relabeling of NORPLANT® above, this will have to be done by the Council, because it is not a high priority for the commercial partner. It is hoped that labeling can be completed by 1999. The cost—approximately \$150,000—will require USAID funding.

### **Recommendation**

28. The team recommends that USAID provide funds so that the Council may apply to the FDA for label changes for both products under the NDAs held by the Council.

**Nestorone® Single Implant.** Nestorone® is a single implant with a two-year life span. This implant will compete directly with the new Organon single implant system (Implanon), which will last three years. Nestorone® has two major advantages over desogestrel: it is not absorbed orally and it does not affect lipid profiles. Thus, a Nestorone® implant would be ideal for lactating women, because it would continue to provide contraception, even after lactational amenorrhea ceases. If the Nestorone® implant could be extended to three years, it would even provide a good method for spacing for women desiring more children. Whether the Nestorone® implant will find a niche for contraception among normally menstruating women is more questionable. Like all long-term progestin-only methods, bleeding disturbances are likely to be unacceptable to some women. Thus, careful consideration should be given to its commercial viability. The lack of an industrial partner and the decision to run down development work on that implant suggest that the Council itself is ambivalent. The Council wants funds to conduct Phase III multicenter trials. It may be best to concentrate such trials in lactating women, because this seems to be the most logical market.

### **Recommendation**

29. If the Council's competitive position with regard to Implanon does not improve significantly within a year or two, consideration should be given to dropping this project, unless a commercial partner is found.

## **Contraceptive Rings**

**Nestorone® Progestin Ring.** Ongoing trials will be completed by late 1998. Bleeding patterns appear to be unacceptable, and no further development will be undertaken except with an industrial partner.

**Nestorone® Progestin/Ethinylestradiol Ring.** The present results look promising. Studies will continue to determine the best dosing schedule and the optimal doses. Those studies should be completed in 1998 and 1999. At that time, a decision will be made on the final product to be used in Phase III trials. In the meantime, a manufacturing method has been developed, and a



commercial partner is now needed. Release rate studies in vitro and in vivo are planned with the factory-made rings to ensure that they behave similarly to those handmade in the laboratory. The Council intends to conduct sufficient clinical studies to file for an NDA. It is hoped that that will be done with a commercial partner. Those studies seem appropriate and should continue.

## **Recommendations**

30. The team concurs with the decisions noted.
31. Because the lack of a suitable ring manufacturer is a serious impediment to progress in developing contraceptive rings, USAID should consider providing assistance in this regard.

## **Intrauterine Delivery Systems**

**Levonorgestrel Intrauterine System.** Development of that system and introduction into the United States now depends on commercial partners. Limited clinical studies are ongoing or planned. None of those studies seem crucial to its introduction. The Council is interacting closely with commercial partners to plan for successful launches in developing countries.

**Nestorone® Progestin Intrauterine System.** The Council believes that development of an IUD releasing Nestorone® is possible because it may have a low level of side effects, it may be highly effective, there may be significant commercial interest, and the cost of the development studies can be spread over all the Nestorone® products. Unlike levonorgestrel, and even though Nestorone® has no effect on lipid profiles, its advantage is mostly theoretical because of the minimal drug levels involved. Furthermore, the Nestorone® IUD is not likely to be any more effective than the levonorgestrel IUD. These findings, as well as the significant cost to develop a new IUD, make this a low-priority product, unless a strong commercial partner can be identified.

## **Recommendation**

32. The team is enthusiastic about promotion of the availability of the LNG IUD, but does not recommend the continued development of the Nestorone® IUD unless the Council is able to present valid arguments for its continuation.

## **Transdermal Delivery for Women**

**Nestorone® Progestin Gel for Women.** Completed studies show that Nestorone® is rapidly absorbed through the skin in amounts adequate to inhibit ovulation. The gel formulation appears to be superior to creams and lotions. Studies underway will establish the optimal dosage, and those studies will be followed by pharmacokinetic and pharmacodynamic studies. It is not clear

whether Nestorone® is intended to be a stand-alone, progestin-only method or if it is intended to be combined with an estrogen as an alternative to oral contraceptives. It does have the advantage of avoiding the first-pass effect through the liver, and, thus, is less likely to cause unwanted side effects such as nausea. The studies to date show that this method is a feasible approach to contraception. It may well stimulate commercial interest for HRT; however, commercial interest in this formulation for contraception may be more problematic.

**Nestorone® Patch Formulations.** Patch formulations provide another approach to transdermal delivery of steroids. Like the gel, the patch avoids the first pass through the liver. The advantage of the patch over a gel is that it can be effective for several days, although it may cause skin irritation in some subjects. The Council intends to develop both a Nestorone®-alone and a Nestorone®-plus-an-estrogen patch. The advantage of the progestin-alone patch, like the progestin-alone gel, over a combined preparation is not clear. The commercial partner is more interested in the patches for HRT than for contraception, but has not ruled out contraception as a possibility. The IND will be completed in 1998, and it is hoped to reach Phase III studies by 2001.

At some point in the near future, it may be necessary to decide whether both gels and patches are to be developed and, if so, what markets are to be served. Nevertheless, both transdermal approaches have the attraction of simplicity and low cost. Patches may be less suitable for developing-country situations.

### **Recommendation**

33. The team recommends that development of both approaches be continued for the present, but within two years it should be possible to select the optimal formulations.

### **Emergency Contraception**

A Nestorone®-only patch has been proposed for emergency contraception, since that method of delivery would avoid the gastrointestinal upset found with the "Yuzpe" regimen. That development will depend on the outcome of the patch development for regular contraception. Although that outcome might provide another emergency contraceptive product, that market is small; unless the promise of use of LNG alone is not fulfilled, the Council patch may be less desirable.

### **Recommendation**

34. The team has little enthusiasm for that approach because of its seeming lack of utility.

## Spermicides/Microbicides

Spermicides/Microbicides is an important area of research. The Council has developed one formulation that seems to have promise. It has been shown that it prevents human simplex virus-2 (HSV-2) infection in a mouse model and that in a limited study is potentially effective against simian immunodeficiency virus (SIV) infection in monkeys. It is not known whether this formulation has any contraceptive efficacy in the rabbit model. This should be a high-priority study because of its affect on the clinical trials and the need to add N-9 to the mixture. N-9 is damaging to the rectal epithelium in mice, and a test is planned to determine whether it has the same affect on humans. There is concern that although this is a potentially very important area, the Council is depending greatly on the success of the one preparation, either with or without N-9. If that preparation fails or if the present formulation proves not to be optimal in field conditions, much work may have to be redone. A good product development strategy for this area should be developed.

### **Recommendation**

35. The Council has developed one formulation that seems to have promise, but future USAID funding for this work should be carefully considered because of overall funding limitations.

## Probing Studies in Female Contraception

The Council intends to continue development of anordiol for emergency contraception. Anordiol has weak estrogenic action and also antiprogestogenic action on the endometrium. It is a potent compound for inhibiting pregnancy in rats. Anordrin, the parent compound, has been used alone and with mifepristone for emergency contraception in China. It is not clear what the advantage of anordiol will be. Its estrogenic actions are likely to cause gastrointestinal side effects unless very low doses are used. Since Phase I trials have not yet been undertaken, the cost to develop this product seems much greater than its potential usefulness, especially given the more advanced status of mifepristone, "Yuzpe" regimen, and LNG. Although adequate toxicology for such usage has been done for anordrin, it is not clear that this is also true for anordiol. Some toxicological issues with anordrin inhibited WHO from undertaking large-scale studies. This project appears to have low priority.

### **Recommendation**

36. The team does not favor research on the use of anordiol for emergency contraception (EC), because the drug appears not to have any advantage over other EC regimens.

## GnRH Immunocontraceptive

Funding is being requested for three aspects of work on this approach not currently funded by NIH: (1) completion of the Clinical Phase II trials, (2) determination of the minimum androgen supplementation required to maintain normal sexual behavior in primates, and (3) correlation of levels of circulating activated complement components with immunocomplexes forming in response to GnRH-TT immunization. No further funding should be given for the following reasons: (1) the uncertainty of suppression of follicle stimulating hormone (FSH) as a contraceptive, (2) the need for androgen supplementation because of luteinizing hormone (LH) suppression (the same as for the simpler and faster-to-develop progestin-androgen combinations), (3) the variable antibody response to the present immunogen, and (4) the lack of suppression of spermatogenesis in the pilot trials.

### Recommendation

37. Although results from the safety study are important for advancing knowledge about immunocontraception and should be published, no further USAID funding should be given on this specific project after completion of the ongoing safety studies, whatever the outcome.

## Androgen Implant (MENT™)

Given that all the approaches to male contraception now under development involve the use of androgen supplementation, the need for a convenient long-acting preparation is paramount. Such a promising lead should have top priority for funding and staff time. It is unfortunate that the toxicology studies to permit longer studies to examine its effect on spermatogenesis, either alone or in combination with another agent, were not started sooner, because progress is now constrained until these are completed. All the proposed studies to be done in the next period are appropriate, important, and should have the highest priority.

### Recommendation

38. The Council should continue to give the highest priority to Androgen Implant (MENT™) work.

## Transdermal Delivery for Men

**MENT™ Gel Formulations.** MENT™ crosses the skin even more readily than Nestorone®, and the Council proposes to develop a MENT™ gel to deliver 1 to 2 milligrams. Optimization of the formulation will be followed by pharmacokinetic studies, and Phase I and II clinical trials.

**MENT™ Patch Formulations.** Similar to the gels, the patch development is at an early stage. It is not possible to determine which approach will prove more viable.

### **Recommendation**

39. These gels and patches for men will clearly be very useful for HRT, but whether compliance will be an issue if they are to be used for contraception is of concern. For this reason, the MENT™ implant would appear to have higher priority for USAID funds at this time.

### **Probing Studies in Male Contraception**

One basic research approach and one applied approach are suggested for funding during the next period. The first approach involves studies of the rearrangement of surface proteins of the sperm surface during epididymal maturation. Study of the epididymis is important because it has been a neglected organ, and also because interference with fertilizing capacity of sperm in that location would ensure a much more rapid cessation of fertility than agents acting on spermatogenesis. The study is intended to examine the action of an as-yet-unidentified protease, which putatively causes the surface redistribution of proteins. This basic question may provide some useful new leads in a field where none are yet obvious.

### **Recommendation**

40. Modest support for this project is recommended until such time as the identity and function of the protease would be more firmly established.

The second project involves the resurrection of compounds that had been previously studied by the Council with NICHD support. New screening techniques are permitting a more cost-effective, faster way to evaluate new synthetic analogs of the original lead compounds. They appear to work by causing exfoliation of immature sperm from the seminiferous epithelium. This approach could provide effective contraception with a once-a-month dosing regimen. If this were the case, questions of general toxicity could be greatly minimized. This project is already being supported by the industrial partner and the consortium for industrial collaboration in contraceptive research.

## Recommendation

41. The studies that will need USAID funding should be clearly identified. A well-defined product development plan should be established to exploit this lead. Collaboration with scientists in the product development group who worked on the related compound previously would be helpful.

### 7.2.2 Expanding Contraceptive Choice

The team looked at the role of ECC beyond the current cooperative agreement by asking two questions. First, should there be a distinct focus or program that addresses ECC issues within the IPD? Second, is the proposed Five-Year Strategic Plan a good basis on which to develop further such a program?

#### Is There a Role for ECC?

The question of whether the Council should have a program that addresses ECC issues was addressed, to a large extent, in the preceding sections of this report. The team sees three basic components of ECC, now and in the future:

1. Appropriate introduction/re-introduction of new and existing contraceptive methods and related technologies,
2. Maximizing access to and quality of program services, and
3. Social and cultural factors affecting contraceptive choice.

The strategic approach that could be used to address those components involves four steps (not all four steps may be needed or feasible in every setting<sup>11</sup>):

1. Identifying barriers to contraceptive choice and use in terms of access to and quality of services,

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<sup>11</sup> Various strategic approaches and methodologies can be applied such as the WHO (Spicehandler and Simmons, 1994) or operations research (Miller, et. al., 1997).

2. Developing a strategy to reduce barriers and improve access to and quality of services,<sup>12</sup>
3. Implementing the strategy, and
4. Assessing the impact of the strategy.

The ECC serves a unique role as a bridge between CBR's contraceptive products and their use in developing-country settings. Until the Council abandons its long-term work in contraceptive development, this need will continue. However, ECC should be more integrally involved in Clinical Phase II programs (Recommendation 11). In addition, ECC should continue to be a source of technical assistance for the introduction of NORPLANT® and the Levonorgestrel 2-rod Implant System, including training and follow-up. Other CAs can and do assist in this role, but the Council should continue to be the lead organization.

The ECC's role in maximizing access to and quality of program services is the one that has the most overlap with other programs within the Council, such as OR and RH. The team sees ECC's unique niche as the program within the IPD that will continue to be most concerned with family planning and methods of contraception. OR's future mandate is very broad, and while family planning is part of its scope, the issue of contraceptive choice and use will by definition be much less important. As mentioned, the overlap between ECC and RH has been allowed to develop and needs to be clarified. The continued existence of ECC would again ensure that family planning is not lost within the broader context of reproductive health.

The links between GFD and ECC have not yet been considered adequately by Council staff, although common interests and perspectives exist—client perspectives and user needs, and life options for girls, such as the "girls and sports" initiative in Kenya. Further, additional areas may exist related to operationalizing quality of care that are not addressed by the Operations Research or MEASURE projects or that could be addressed jointly by ECC and another project (as has happened in Zambia and Senegal).

The third component of ECC, social and cultural factors of contraceptive choice, is most closely related to some of the research studies in the PRD. The team sees the desirability of much stronger ties between PRD and IPD, especially in developing interventions based on the PRD research (Recommendation 18), and considers ECC to be a potential avenue to accomplish this link. Otherwise, a new entity could be established.

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<sup>12</sup> Factors that affect choice include many access, quality, and image variables, including supply of commodities (e.g., registration of products), restrictive program policies and practices, psychosocial barriers, range or mix of methods, technical competence, client-provider interaction and counseling, and so forth (Bruce, 1990 and Bertrand, Magnani, and Knowles, 1994). The capacity of the service delivery system and the social and cultural setting are also key factors.

## Comments on Appropriate Application of Technology in the Strategic Plan

The team sees the proposed plan for ECC as a good beginning. The team agrees in general with the "three overarching components," but with a few wording changes as noted. The emphasis on contraceptive technology should be retained. The team also cautions against the Council's adopting too broad a mandate in introducing all technologies, and favors continued concentration on contraceptive technologies. Similarly, we believe that the title of the program should not change. Although the ECC name is not well recognized, if it remains as a distinct program within the IPD, another change of name to "appropriate application of technology" will not help; such a name is so general that it may not be useful. Again, the emphasis on contraception will be very important for the future of any ECC program.

In the description of program structure, the need to "provide technical assistance to research and demonstration projects being implemented by other Council programs" is important. In addition, the team sees a need to develop and implement a research agenda on ECC issues. At present, ECC activities are 100 percent responsive to field needs. Although this responsive mode is congratulated, an important role for a more proactive research agenda exists. The ideas for the agenda would come from ECC staff in concert with other Council staff (IPD and PRD) and with some outside groups or individuals as well—other players including other CAs in the USAID MAQ initiative, for example. One research topic suggested in the course of this evaluation involves looking at four to five countries with only one method or a skewed method mix to learn (1) how they developed as they did, (2) if a change was or is needed, (3) what should be (is being or has been) done to improve the method mix, and (4) what lessons are being learned from such efforts. (This suggestion is similar to Recommendation 3.) Another topic proposed by ECC (Recommendation 7) is developing criteria for method mix. The team believes that this and other such topics could become the basis for an ECC research agenda.

The team thinks it of utmost importance that the proposed plan be thoroughly evaluated within the IPD (both headquarters and regional staff), in conjunction with PRD. Only through this process can the role of ECC be properly defined and well-integrated with other Council programs.



## **APPENDICES**

## APPENDIX A

### POPULATION COUNCIL PROGRAMMATIC AGREEMENT EVALUATION TEAM SCOPE OF WORK

#### I GENERAL BACKGROUND

The Population Council, an international, nonprofit organization, undertakes social science and biomedical research, advises and assists international agencies and governments, and disseminates information on population issues. Established in 1952, the Council is governed by a Board of Trustees whose members come from over ten countries. The Council is committed to the enhancement of human welfare and works in three areas: 1) biomedical research to develop reproductive health technologies, including contraceptive methods for women and men, 2) social science research into the causes of population change, their societal implications, and appropriate policy responses, and 3) provision of technical assistance to family planning and other population-related programs at local, national, and regional levels. In addition, The Population Council supports advanced training for population specialists. The Population Council disseminates its findings by producing publications for researchers, policymakers, and the concerned public. To carry out its work, The Council is organized into the Center for Biomedical Research (CBR), Policy Research Division, International Programs Division, Office of Development, and Corporate Affairs.

The Center for Biomedical Research endeavors to develop and improve technologies to enhance the reproductive health of women and men. Much of the work conducted in their basic science group is focused on elucidating the mechanisms of human reproductive physiology, especially in the male. Their product development group focuses on clinical evaluation and regulatory approval of new technologies. In recent years, the product development group's efforts have expanded beyond family planning methods to include products for hormone replacement treatments and development of vaginal microbicides.

The Policy Research Division seeks to contribute to the understanding of population policy issues and to advance applications of that knowledge to the design of policies responsive to both individual and societal needs. These goals are pursued through a program of social science research by division staff.

The International Programs Division conducts field based operations which bring the Population Council into working

partnerships with policymakers and population professionals in developing countries. The Population Council maintains area offices in several regions: Latin America, Asia, East Africa, West Africa, and the Middle East. A multidisciplinary professional staff in New York provides interregional support and coordination. Areas of current work include Expanding Contraceptive Choice (ECC), Family Planning Programs, Reproductive Health, Gender, Family and Development, and Population Policy.

From the base of the work undertaken in the Center for Biomedical Research, the Population Policy Division, and International Programs Division, the Office of Communications (within Corporate Affairs) publishes and disseminates scientific information to professionals and to a broader audience of policy makers and nonspecialists. The Office produces the Council's two journals, Population and Development Review and Studies in Family Planning, in addition to numerous books, pamphlets, and brochures.

## II THE OFFICE OF POPULATION COOPERATIVE AGREEMENT AND OTHER USAID-SUPPORTED ACTIVITIES OF THE POPULATION COUNCIL

The current Cooperative Agreement between the United States Agency for International Development (USAID) and the Population Council, No CCP-A-00-94-00013-04 (formerly CCP-3050-A-00-4013-00) provides support for the period 30 September 1994 through 30 September 1999. The purpose of this agreement is to support the Population Council's programs to improve family planning technology available for use in developing countries and to improve the delivery and use of family planning services in the developing world. Areas supported under the agreement are a) Contraceptive Development (through the product development subdivision in the Center for Biomedical Research), b) Expanding Contraceptive Choice, and c) Policy Research.

At the time of this workscope preparation, The Population Council holds several other agreements with USAID, including

- a three contracts to conduct family planning operations research (OR) and technical assistance in three regions: Latin America, Asia, and Africa, supported by the Research Division, Office of Population,
- b a cooperative agreement to conduct activities related to development of a vaginal microbicide(s), supported by the HIV/AIDS division, Office of Health and Nutrition,
- c a cooperative agreement to carry out Operations Research on HIV/AIDS programs recently awarded by the HIV/AIDS division, Office of Health and Nutrition, and

d a number of agreements with USAID missions to carry out research in the field of reproductive health

Evaluation reports of the above activities (with the exception of c and d ) will be supplied to the evaluation team to provide a broader understanding of the role of USAID, and of this cooperative agreement in USAID's overall support of the Population Council's activities

### III USAID-SUPPORTED PROGRAMS under the Office of Population Cooperative Agreement

#### A Contraceptive Development

The Population Council Center for Biomedical Research (CBR) laboratories are located at Rockefeller University, New York. The CBR personnel, which includes 22 principal scientists, 22 postdoctoral fellows, and additional technical support staff, seek to improve technology for enhancing reproductive health of women and men.

The CBR staff work primarily in applied research and development of new methods of contraception for women and men. In the past five years, there have been several changes in leadership. Dr. C. Wayne Bardin was the former Director and Dr. Rosemarie Thau was the former Associate Director for Product Development of the Center for Biomedical Research. For an interim period of several months, Dr. James Catterall, the Director of Basic Sciences, served as Acting CBR Director. In 1996, Dr. Elof Johansson became the CBR Director and Vice President for Biomedical Affairs. Dr. Anne Robbins, who had taken on a leadership role in the product development group, left the Council in October, 1997. Currently, Dr. Johansson is both Vice President for Biomedical Research and Acting Associate Director for product development.

The contraceptive development program personnel strive to identify, develop, and evaluate promising leads for new contraceptives, especially those that will be useful in developing countries. A principal instrument for this effort is the International Committee for Contraception Research (ICCR), which consists of clinical experts from several countries who serve as investigators in the clinical evaluation of potential methods. The members of the ICCR meet biannually to review clinical results, develop clinical protocols and provide general direction and feedback to product development activities. These activities are supplemented by studies conducted within the Council's laboratories, by contracts placed with other clinics and laboratories, and by cooperative agreements with industry.

During the course of this agreement, support was provided for contraceptive development for women including NORPLANT implants, 2-rod levonorgestrel subdermal implants (formerly known as NORPLANT II), several hormone-releasing contraceptive vaginal rings (CVRs), a levonorgestrel-releasing intrauterine system (IUS) (formerly known as the intracervical LNG device--ICD), NESTERONE toxicology, transdermal NESTERONE delivery, and a

NESTERONE single subdermal implant    In addition, funding was  
provided for a New Drug Application (NDA) for the 2-rod  
levonorgestrel subdermal implants

Support was also provided for contraceptive development for men including LHRH analogs, MENT toxicology, MENT implant development, MENT transdermal development, LHRH vaccine, and the Vassoclude device for male sterilization

B Expanding Contraceptive Choice (ECC) Program

The program to expand contraceptive choice was, historically, primarily aimed at facilitating the widest availability and most appropriate use of contraceptive technologies developed by the Council the Copper T 380A intrauterine device and NORPLANT contraceptive implants In 1992, the program matured to include all safe and effective contraceptive technologies Although The Council has expanded its work beyond its own products, ECC personnel continue to play a role in product management-for Population Council-developed methods, especially NORPLANT implants Much of their work is accomplished in the mode of technical assistance and policy-level facilitation to improve the availability and use of safe and effective family planning methods

The number of ECC program personnel is relatively small There were two-senior level technical staff in New York, the Director of Family Planning and the ECC Associate Recently, the Director of Family Planning took another role within The Council, and the ECC Associate has been promoted to the position of ECC Director The program also supports up to two junior-level personnel and an administrative assistant to the ECC Director NY-based staff provide overall technical expertise and program direction They often interact with USAID staff and The Council's cooperating agency colleagues to move forward the understanding of how family planning technologies might appropriately mesh into the infinitely different, and sometimes difficult, service delivery settings

There are currently three regional Medical Associates who are responsible for managing the regional programs Brazil-based Dr Juan Diaz, Kenya-based Dr Davy Chikimata, West Africa-based Dr Penda N'Diaye In addition to the regional medical associates, there are two India-based associates, Dr Sandhy Joshi (a social scientist), and Dr Rohit Bhatt Formerly a part-time consultant, Dr DeZoysa's ended her affiliation with the ECC program in October, 1997 as she is now working on the USAID-supported Horizons HIV/AIDS project The ECC program also supports a Kenyan-based social scientist, Mr John Skibiak, who works mostly with the Zambian program in close collaboration with the WHO Task Force on Technology Transfer and Introduction

A major emphasis of the interregional staff in the past few years has been to broaden the scope of contraceptive introduction to include a wider choice of methods, such as Depo-Provera and the diaphragm. This expansion matured as The Council's close ties with the WHO Task Force on Technology Transfer and Introduction resulted in a new approach that has evolved into a research-based, participatory, strategic methodology for determining the most appropriate method mix for the local service delivery capacity, taking into account local client cultures and preferences. This strategy has enabled the Population Council to assist family planning program managers to assess the range of contraceptive choices currently available to clients, overcome constraints to the use of specific methods, such as medical barriers, and then to develop local strategies for introduction or reintroduction of various family planning methods. Two country strategies supported during the course of the current agreement are Zambia (mainly through the efforts of Dr. John Skibiak) and Brazil (mainly through the efforts of Dr. Juan Diaz).

Medical Associates work at the medical and policy-making levels to enhance contraceptive choice, especially in countries or situations where constraints are strong. For example, although use of injectables is very low in Brazil (as elsewhere in the LAC region) the government expressed interest in including Depo-Provera in its programs, and The Council Medical Associate is responding by coordinating with USAID and other cooperating agencies to promote expanded choice through the availability of injectable contraceptives throughout the country.

The Medical Associates often collaborate with the Population Council's Operations Research (OR) staff on studies related to enhancing quality family planning services, especially in expanding contraceptive choice in service delivery settings in the region in which they work. NORPLANT implants remain the main focus of the East and South Africa activities. In the area of product management, staff work with manufacturers and licensees on issues of technology transfer to developing countries, public sector pricing, and the introduction of Population Council-developed technologies.

In the past, many decisions as to which research activities to support and where to implement such activities were centrally determined. However, with the advent of USAID's field support planning mechanism and the almost concurrent decentralization of the Population Council ECC program, planning and global strategy implementation of field-based activities has become, in general, more complicated.



C     Policy Research Division

In contrast to the support the Biomedical and Expanding Contraceptive Choice programs receive for their program as a whole, the Policy Research Division receives funding for activities on a case-by-case basis. The current cooperative agreement supported following activities in the Policy Research Division

1 Navrongo Family Planing Program Design, Implementation, Evaluation, and Dissemination

Principal Investigator Dr Jim Phillips

Dr Phillips has worked closely with the Community Health and Family Planning project to document the impact of family planning in African settings. In his work, Dr Phillips works closely with the Africa OR/TA program and the Ghanaian Ministry of Health to provide technical assistance to the pilot phase and expansions of this experimental demonstration program.

2 Understanding and Meeting the Needs of Adolescents

Principal Investigator Dr Barbara Mensch

Dr Mensch and her colleagues are investigating the context in which early sexual activity and childbearing take place, especially in relationship to girls' education and gender roles. Reports of this work, which has been conducted in Kenya and is planned for Egypt, have been presented at the National Academy of Sciences and USAID.

EVALUATION SCOPE OF WORK

A spring, 1998 evaluation will be conducted at the Washington, D C offices of USAID, the Population Council offices and laboratories in New York City, and two other field sites by the team members. The purpose of this evaluation is to assess Population Council's performance under the Programmatic Cooperative Agreement CCP-A-00-94-00013-04 (formerly CCP-3050-A-00-4013-00) for activities conducted during the period from September 1994 through Spring 1998 and make strategic recommendations for possible future activities. This evaluation will essentially update the previous comprehensive five year evaluation conducted in 1994. The evaluation team will seek to examine both broadly and on a project-specific basis, the activities and impact resulting from funding over the past five-year period of the agreement. The evaluation team should analyze the general portfolio and accomplishments of the program, the development and implementation of specific activities, project management, reported and monitoring and evaluation of sub-activities, and collaboration and relationships with other organizations in the biomedical field (eg Family Health International, (FHI), Contraceptive Research and Development Program, (CONRAD), AVSC International, World Health Organization, (HRP), and others.)

Importantly, since USAID is interested in determining whether a follow-on program should be funded, and *if so*, identifying possible ways in which a follow-on program might be improved, we request that the team focus on the Population Council's directions proposed for research over the coming five years, (the team will be supplied with the Council's five year strategic plan) and discuss, when possible, how these proposed activities will complement those of other programs supported by USAID and other donors. The team will also be tasked with thinking strategically as to what issues and technologies will be most important in the next ten years. A list of information to be provided to the team, as well as issues to be addressed by the team, is set out below.

## B Data Sources and Data To Be Collected

### 1 Existing Sources of Information

The evaluation team should review both the report of the previous comprehensive five year evaluation from 1994 and the Population Council's response to the recommendations made following this evaluation. As the cooperative agreement essentially supports ongoing Population Council activities, USAID will also provide the team with all available final evaluations from the other USAID-supported activities at the Population Council. To review the activities undertaken under the current cooperative agreement, the team will be supplied with the annual progress reports and the most recent ICCR reports. If possible, the evaluation will be timed so that the biomedical and managerial members of the evaluation team may attend the spring ICCR meeting in early April. To understand the current personnel cadre, curriculum vitae of relevant employees and contractors will be provided. The team will also receive copies of the various USAID-supported booklets and outreach efforts disseminated via the Population Council's Office of Communication. Finally, in order to appraise the Population Council strategic plans for the next several years, the Council has been requested to prepare a five year plan of proposed activities for review by the evaluation team. In order to fully understand how the Population Council compares/contrasts with our other contraceptive technology activities, the evaluation team will be provided with annual reports from FHI and the CONRAD program, and are requested to contact representatives of those CAs.

USAID/W will be available for face-to-face interviews and phone consultation during the entire evaluation period. To provide USAID field mission feedback, responses to a worldwide inquiry

email regarding the activities conducted under the cooperative agreement will be provided to the evaluation team

### 3 Questions for the Evaluation Team's consideration

#### a General Administration \* = priority question

Is the administration of this multidivisional agreement handled in the most effective manner, or can improvements be made?

\*How well has the Population Council responded to USAID's reengineering, particularly regarding timely submission of workplans and reports in the required USAID strategic framework format?

#### b Technical General Issues

\*To what extent does the Population Council use USAID's funds to maximal advantage? Is the manner in which USAID funding is used within the context of Population Council's Donor portfolio efficient? Are leverages gained or missed?

How do the activities supported by this agreement complement or duplicate other USAID supported activities, both at Population Council and with the other CAs?

\*Is the funding level of the current Cooperative Agreement sufficient to move forward to accomplish USAID's Strategic Objectives? Can new leads and ongoing programs be adequately pursued?

\*How well does the Population Council disseminate results from activities undertaken with support from the cooperative agreement? Who are the target audiences? Are there clear examples of positive changes that have occurred on account of The Council's dissemination activities at the program level?

#### c Overall Staff Pattern Funded by USAID

\*Is appropriate staffing, in terms of both level and expertise, sufficient to meet the needs of all of the various areas covered with USAID cooperative agreement funding? Are there gaps or lack of primary- or secondary-level personnel?

Is subproject oversight by Population Council staff effective and efficient?

Is there appropriate use of consultants, or too little or too much?

#### d The Contraceptive Development Portfolio

The evaluation team should examine the projects being supported under the contraceptive development portfolio in order to determine their potential value to USAID's development assistance effort and recommend possible future changes in their USAID-funded portfolio and recommend funding levels. The team should examine The Council's five year plan for future product development and discuss any hurdles they perceive for the methods currently under development, addressing what these hurdles might mean in terms of funding needs and constraints to development. The team is urged to pay special attention to issues surrounding the agreements that Population Council enters into with private industry to develop contraceptive products with USAID financial support, specifically, has every possibility been explored to ensure the lowest possible price to the public sector?

\*How are activities progressing in regard to actively engaging the private sector in development and marketing of new contraceptive products? What are the barriers that need to be overcome in order to enhance the ability of the public sector to enter into agreements that ensure receive the lowest possible price to public-sector agencies?

\*Are the systems currently in place enough to ensure the efficiency of reaching the goal of a market ready contraceptive in the shortest amount of time and at the lowest cost?

\*Is the most effective product-lead prioritization scheme in place? If not, what recommendations would the team make for improvements. Is there a strong team of appropriate people involved in reaching a decision point regarding the contraceptive product's potential (feasibility, impact, cost) and acceptability?

\*Are the current processes for internal and external review(s) adequate?

\*Is the current approach to preparation of INDs/NDAs and IDEs/PMA's satisfactory? Are there areas in which the above capacities could be streamlined/strengthened? To what extent do commercial partners handle this work? Should such work be subcontracted?

\*What types of assurances are made to ensure that Council-developed contraceptive products are labelled with the maximum use life that data justify?

\*How well does the work ongoing at the Population Council fit the field needs of developing country programs and the needs of women in low socio-economic settings?

\*Are important areas for new technologies missed, perhaps for reasons of funding? If so, what are they, and how much effort should be spent on these areas?

Is there any unnecessary duplication or overlap with other R&D efforts? (Note the team will be supplied with a contact list of other leaders in the contraceptive development field )

\*To what extent is there an interactive coordination between both the staff of the Center of Biomedical Research and the other programs within The Council, including the ECC staff? What has been the outcome?

\*To what extent does the feedback from groups external to the CBR, and even external to the Population Council, such as donors and women's health advocates, influence their decision-making process? Is there a positive or negative impact?

#### e Expanding Contraceptive Choice

\*How well has the ECC program coordinated with the OR projects and vice-versa? Is there unnecessary duplication or overlap? Should ECC activities be rolled into the new OR/TA procurement (FRONTIERS)?

What unique role(s) do the ECC field associates fill?

\*Should USAID continue to support these activities or a modification of these activities? If yes, via what mechanism and to what level?

\*Are the overall research staff strengths/skills/numbers appropriate for its past and future program? Are consultants utilized efficiently and effectively?

\*What role did the former Director of Family Planning, Dr Andrew Fisher, play in advancing the ECC program? How has the staff turnover in the family planning director position impacted the program?

\*Please provide an overall assessment of the current ECC activities for both product introduction and product "reintroduction", addressing past and ongoing activities, and possible missed opportunities in regard to

- a soundness of research methodologies/technical assistance used for the introduction/reintroduction of contraceptive methods,
- b appropriate expansion of method mix, and
- c positive influences of ECC program on local policies and programs

Has the ECC program coordinated well with other organizations (e g other USAID CAS and WHO) especially in regard to Maximizing Access and Quality, the interagency study of diaphragm acceptability and feasibility and, importantly, the strategic approach to enhancing the family planning method mix in various settings?

\*To what extent is there an interactive and collegial coordination between both the staff of the Center of Biomedical Research and the Expanding Contraceptive Choice staff? What has been the outcome?

\*How well have the Population Council field representatives adapted to the reengineered reporting practices and understood and worked within the new USAID field support system?

#### f Policy Research Division

Are decisions made well as to when and how USAID's funds are utilized? Are USAID's funds well-leveraged? Are there any major missed opportunities for USAID's support to this division?

Are the overall research staff strengths/skills and numbers appropriate for its mission?

To what extent does the data/information garnered from these studies influence local country programs and the policies of countries in which the studies are conducted?

\*Is this an effective use of USAID's funds?

\*Should USAID continue to support these activities? If so, to what level?

#### g Relationship of the Program with USAID - strengths and Weaknesses

\*How are working relationships with USAID Washington Staff, especially with the Technical Advisor, Cognizant Technical



Officer, other Research Division and PHN Center staff, and staff from the Office of Procurement?

\*Does the team have any recommendations for improvement?

\*How are relationships with USAID's PHN officers in the field?

\*Does the team have any recommendations for improvement?

#### V TEAM COMPOSITION AND SIZE

The evaluation team should consist of four members. There should be two members with extensive experience in contraceptive research and development as well as the USFDA approval process to evaluate the program at the Center for Biomedical Research. Preferably, one of the biomedical scientists would also have advanced management training and a keen understanding of the programmatic reality of service delivery systems in many developing country settings. The second biomedical scientist should have product development experience and expertise in working with the private sector.

The two members designated to evaluate the program of Expanding Contraceptive Choice and the Policy Research Division activities should have extensive family planning program experience in the developing world, senior family planning program managers and/or policymakers would be ideal. One of the ECC evaluators should also have some medical/clinical expertise with a good understanding of contraceptive technologies.

Evidence of solid writing skills is also important. The team leader who should be one of the above evaluators, should be assigned the task of integrating sections of the preliminary report drafted by other team members, in which case writing and editing skills will be particularly important for this team member.

#### VI PROCEDURE OF EVALUATION\*

(\*Please note that the procedure is flexible, and is still being revised as members are chosen, and plans finalized with the Population Council and PPOTECH.)

The Evaluation Team will meet for three days in the Rosslyn, VA offices of Poptech. Prior to their arrival, the team will be supplied with the information defined under "Existing Information" and those questions to which the Population Council has been requested to provide their perspective. The team will

be provided approximately three days to familiarize themselves with this background information. On Day One, the evaluation team will be briefed on process by the contractor and, review schedules/procedures. During the second two days, the team will use some of their time to interview USAID personnel and local cooperating agency representatives and review cable responses from USAID field missions. Phone interviews will also be possible.

The team will then travel to New York to the Population Council Headquarters for three days of site visits. On the first day, all members should attend one day of presentations by the Population Council's Center for Biomedical Research, Expanding Contraceptive Choice Program, and Policy Research Division staff. On the second and third days, the evaluation team should meet with their respective divisions. Visits or phone calls may also be made to NY-based cooperating agencies. Note: team will be provided with a contact list of non-Population Council-based program directors in the field of reproductive health.

#### A ECC Evaluation Team

During the New York visit, the ECC team will meet with key staff members including Dr. George Brown, Ms. Martha Brady, Dr. Jim Phillips and Dr. Barbara Mensch. Dr. Andrew Fisher should be contacted, although he will most probably be accessible during the Washington, DC portions of the evaluation.

From there, the ECC team members will travel to Campinas, Brazil to spend two days with Dr. Juar Diaz to visit project sites and have time for extensive discussions with Dr. Diaz, USAID Mission personnel, and Cooperating Agency representatives. From Brazil, the team members will travel to Nairobi, Kenya for three days to conduct a parallel schedule with the African Medical Associates, Dr. Davy Chikimata and Dr. Penda N'Diaye (who will travel to Kenya for the evaluation). Depending on the final schedule, the team may be asked to travel to New Delhi to meet with Population Council representatives.

#### B CBR Evaluation Team

The biomedical scientists on the evaluation team will stay on in New York for one or two additional days (for a total of four to five days in NY) to meet with members of the CBR. It is hoped that the team will be visiting during the spring ICCR meeting, allowing close discussion with the clinical investigators. The team should meet with CBR director Dr. Elof Johansson and all other senior CBR members, at the team's request. Ms. Sandra Arnold, Vice President for Corporate Affairs and Mr. Young should

be involved in discussions regarding enhancing private sector partnerships. Former CBR and Contraceptive Development Directors, respectively, Dr C Wayne Bardin, Dr Rosemarie Thau, and Dr Anne Robbins should be contacted.

#### VII Finalization

The entire team will reconvene in Rosslyn, Virginia to write the report and debrief USAID staff. The team leader will be responsible for submitting the completed final report in a timely fashion, preferably by the first week in June, 1998.

## Appendix 1

### Population Council written preparations for the evaluation

The Population Council will prepare responses to the following questions in order to help the evaluation team spend its time most effectively

#### a General Questions

Who is responsible for the administrative requirements of the cooperative agreement?

How does the Population Council decide how much USAID money goes towards each product and/or activity?

To what extent do non-USAID funds fill gaps in program or vice versa? How is USAID funding used within the context of Population Council's Donor portfolio? Are efficiencies/leverages gained?

How are activities reviewed "internally" and "externally"?

#### b Center for Biomedical Research

What are the processes and who are the persons involved in reaching a decision point regarding the contraceptive product's potential (feasibility, impact, cost) and acceptability?

When the Population Council enters into agreements with private industry to develop contraceptive products with USAID financial support specifically, what processes are in place to ensure that every possibility has been explored to ensure the lowest possible price to the public sector?

What types of systems are in place to ensure the efficiency of reaching the goal of a market-ready contraceptive in the shortest amount of time and at the lowest cost?

What is the current approach to preparation of INDs/NDAs and IDEs/PMAs? Are there areas in which the above capacities could be streamlined/strengthened? To what extent do commercial partners handle this work? Should such work be subcontracted?

To what extent does the feedback from groups external to the CBR, and even external to the Population Council, such as donors or women's health advocates, influence their decision-making process? Is there a positive or negative impact?

### Expanding Contraceptive Choice

What role did the former Director of Family Planning, Dr Andrew Fisher, play in advancing the ECC program? How has the staff turnover in the family planning director position impacted the program?

How does the ECC program coordinate with others (e g other USAID CAs and WHO), especially in regard to

- a Maximizing Access and Quality,
- b the interagency study of diaphragm acceptability and feasibility, and, importantly,
- c the "strategic approach" to enhancing the family planning method mix in various settings?

### d Policy Research Division

How are decisions made as to when and how USAID's funds are utilized? Are USAID's funds leveraged--and if so, how?

What role does the data/information garnered from these studies feed into both global and local country programming and policymaking?

## APPENDIX B

### Bibliography

Adamchak, Susan, Willa Pressman, Alpha Sy, and Pamela Wolf, *Evaluation of the Africa Operations Research/Technical Assistance Project II*, POPTECH, Arlington, VA, February 1998.

Bertrand, Jane, Robert J. Magnani, and James C. Knowles, *Handbook of Indicators for Family Planning Program Evaluation*, The Evaluation Project, Carolina Population Center, University of North Carolina, Chapel Hill, NC, 1994.

Harper, Michael J.K., Michael J. Free, Laura Laski, and Robert Wickham, Final "Evaluation of the Population Council Activities Conducted Under the Cooperative Agreement," prepared for the Office of Population, U.S. Agency for International Development, November 1-17, 1993.

McCauley, Ann P. and Judith S. Geller, "Decisions for Norplant Programs," *Population Reports*, Series K, No. 4 Baltimore, Johns Hopkins University, Population Information Program, September 1992.

Miller, Robert, et. al., *The Situation Analysis Approach to Assessing Family Planning and Reproductive Health Services: A Handbook*, The Population Council, Inc., 1997.

Population Council, Programmatic Activities, "Contraceptive Development, Contraceptive Introduction, Family Planning and Related Health Services, and Policy Research, 1994-1999 (revised proposal for five years of programmatic activities)," March 31, 1994.

Spicehandler, Joanne and Ruth Simmons, *Contraceptive Introduction Reconsidered: A Review and Conceptual Framework*, Task Force on Research on the Introduction and Transfer of Technologies for Fertility Regulation, Special Programme of Research, Development and Research Training in Human Reproduction, World Health Organization, Geneva, 1994.

Simmons, Ruth, et. al., "The Strategic Approach to Contraceptive Introduction," *Studies in Family Planning*, Vol. 28, No. 2, June 1997.

U.S. Agency for International Development, "Strategic Plan for the Center for Population, Health and Nutrition," Bureau for Global Program, Field Support and Research, December 1995.



## **APPENDIX C**

### **List of Contacts**

#### **Population Council**

##### **Administration**

Mrs. Margaret Catley-Carlson, President

##### **Corporate Affairs**

Sandra Arnold

##### **Grants and Contracts**

Netania Budofsky

Kristin Morrell

#### **Center for Biomedical Research**

Dr. Elof Johannson

Mr. Arthur Allen

Dr. Indrani Bagchi

Dr. Ashton Barfield

Dr. James Catterall

Mr. Peter Conlon

Dr. Glen Gunsalus

Dr. Gary Hunnicutt

Dr. Theodore Jakanicz

Dr. Sam Koide

Dr. Alfred Moo-Young

Dr. Harold Nash

Dr. David Phillips

Dr. Frederick Schmidt

Mr. Irving Sivin

Dr. Irving Spitz

Dr. Kalyan Sundaram

Dr. Yun-Yen Tsong

#### **International Programs Division (IPD)**

George Brown

Ian Askew

Martha Brady

Judith Bruce

Juan Diaz



Andrew Fisher  
James Foreit  
Anrudh Jain  
Joanne Gleason  
Valerie Moulay-Omar  
John Townsend  
Beverly Winikoff

**IPD Field Staff in Kenya, Senegal and Zambia**

Ayo Ajayi  
Lucy Chege Abubaker  
Davy Chikamata  
John Kekevole  
Esther Muia  
Penda N'Diaye  
Kathleen Siachitema  
John Skibiak

**IPD Field Staff in India**

Sandhya Joshi

**IPD Field Staff in Brazil**

Juan Diaz

**Policy Research Division**

John Bongaarts  
John Casterline  
Barbara Mensch  
James Phillips

**USAID**

**USAID/Washington**

Felice Apter  
Duff Gillespie  
Sarah Harbison  
Marge Horn  
Mihira Karra  
Karin Ringheim  
Jim Shelton  
Jeff Spieler  
Ellen Starbird

**USAID/Brazil**

Maria Etelvina Toledo Barros  
Maria Filomena V. S. Lentini  
Maria Luiza Lins

**USAID/Kenya**

Hanna Dagnachew  
Jerusha Karuthiru

**USAID/Zambia**

Paul Hartenberger

**AVSC**

Lynn Bakamjian  
Mark Barone  
Karen Beatty  
Amy Pollock

**CONRAD**

Henry Gabelnick

**FHI**

Ward Cates  
Laneta Dorflinger

**ICRW**

Joanne Spicehandler

**JHPIEGO**

Noel McIntosh

**Quintiles/Georgetown University**

Peter O'Hanley

**Rockefeller Foundation**

Mahmoud Fathalla

**WHO**

Gabriel Bialy  
Jane Cottingham  
David Griffin  
Patrick Rowe  
Paul Van Look

**Independent Consultant**

Egon Diczfalusy

**Other contacts in Brazil**

Margarita Diaz

**Other Contacts in Kenya**

Nelson Keyonzo, Pathfinder International

John Wilson, John Snow, Inc

**Other Contacts in Zambia**

Yousef Admed, University Teaching Hospital

Oliver Chinganya, Central Statistics Office

Ms. Kafula, University Teaching Hospital

Dean Phiri, Central Board of Health, MOH

Tamara Feters, CARE International

Mary Zama, MOH/CARE Project

District Health Management Team, Npongwe

Dr. Soka,

Mr. Banda

Npongwe Mission Hospital

Dr. Enyan

Health care providers

District Health Management Team, Masaiti

Dr. Bernard Maswane

Mr. Zulu

Kafulafuta Mission Hospital

Ms. Bupe

Masaiti Council Clinic

Mrs. Musonda

Mr. Mulenga

**Appendices D, E, F, G, H, I, J, K, L, and M available in hard copy**

## **APPENDIX N**

### **Financial Tables**



**Table N1**

**Sources of Support for 1997 Activities\***

<b>Source</b>	<b>Amount (\$)</b>	<b>Percentage (%)</b>
U.S. Government		
<i>Agency for International Development</i>	24,161,252**	48
<i>National Institutes of Health</i>	4,027,399	8
Total U.S. Governments	28,188,652	56
Other Governments	3,539,474	7
Multilateral Organizations	2,503,783	5
Foundations, Corporations, Other Nongovernmental Organizations, and Individuals	9,352,185	19
Council (Internal) Funds	6,473,261	13
<b>Grand Total</b>	<b>50,057,355</b>	<b>100</b>

*Source:* The Population Council

\* Excluding activities associated with mifepristone

\*\* Including Cooperative Agreement total of \$6,353,874

Table N2

## Contraceptive Development Direct Costs

	Percentage by Funding Category										
	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	Average
U.S. GOVERNMENT	54	50	44	48	44	46	45	42	53	60	49
<b>USAID programmatic cooperative agreement</b>	<b>50</b>	<b>46</b>	<b>40</b>	<b>46</b>	<b>37</b>	<b>35</b>	<b>34</b>	<b>31</b>	<b>40</b>	<b>42</b>	<b>40</b>
USAID microbicides cooperative agreement	0	0	0	0	0	0	1	2	2	2	1
National Institutes of Health	4	4	4	3	7	11	10	9	10	16	8
OTHER GOVERNMENTS, MULTILATERALS	13	10	10	9	10	6	9	13	9	11	10
OTHER POPULATION AGENCIES	0	0	0	0	1	2	0	0	0	3	1
FOUNDATIONS*, TRUSTS, INDIVIDUALS	26	27	33	30	27	27	28	25	23	19	27
INDUSTRY**	0	0	8	6	14	16	15	18	13	0	9
POPULATION COUNCIL UNRESTRICTED	7	13	5	6	4	4	3	2	3	7	5
	100	100	100	100	100	100	100	100	100	100	100

Source: The Population Council

\* Decreases in funding from Mellon and Rockefeller Foundations replaced by other sources.

\*\* Primarily Wyeth support for NORPLANT and NORPLANT II clinical trials.



**Table N3**

**International Programs Division  
Population Council Expenditures and USAID Funding, 1994-1997**

	Expenditures/Funding Per Year (in \$000)			
	1994	1995	1996	1997
PC Total Expenditures	44,437	56,852	50,446	52,017
IPD Total Expenditures	18,689	22,926	23,003	26,858
IP as % of Total PC	42.1%	40.3%	45.6%	51.6%
Total USAID funding to IP	10,494	15,196	14,569	17,967
Cooperative Agreement to IP*	1,782	2,139	3,570	2,318
ECC	1,082	1,138	1,753	1,274
Bangladesh	311	838	1,694	922
Africa		163	123	122
Other	389			
USAID as % of total IP	56.2%	66.3%	63.3%	66.9%
Cooperative Agreement as % IP	9.5%	9.3%	15.5%	8.6%
Cooperative Agreement, ECC only as % IP	5.8%	5.0%	7.6%	4.7%

*Source:* The Population Council

\* In 1994, most Cooperative Agreement Expenditures were under 8059 (only 38 [000] under 4013); In 1995, 338(000) of the Cooperative Agreement expenditures were under 8,059.

**Table N4****ECC Program Expenditures 1994-1997**

	Expenditures per Year (in \$000)				
	1994	1995	1996	1997	Total
ECC Total Expenditures	1,619	1,662	1,917	1,499	6,697
USAID Cooperative Agreement	1,082	1,138	1,753	1,274	5,247
WHO	147	136	61	82	426
Government of Kenya/World Bank	112	78	-	40	230
UNFPA	222	258	91	93	664
Population Council	56	51	12	10	129
USAID as % of total ECC	66.8%	68.5%	91.4%	85.0%	

**Table N5**

**Policy Research Division  
USAID - Cooperative Agreement Funding, 1995-present  
Direct Costs**

<b>Year</b>	<b>Total Budget PC</b>	<b>Total Budget PRD</b>	<b>Total Cooperative Agreement</b>	<b>Cooperative Agreement PRD</b>	<b>CA for PRD as % of Total CA</b>	<b>CA for PRD as % of Total PRD</b>	<b>Experimental Research</b>	<b>Adolescents</b>
1995 Yr	30,042,699	2,232,972	5,820,651	63,567	1.1	2.8	30,155	33,412
1996 Yr 2	29,983,481	2,240,772	7,626,311	191,768	2.5	8.6	133,603	58,165
1997 Yr 3	37,000,000	2,380,582	4,822,173	232,494	4.8	9.8	150,105	82,389
1998 Yr 4	46,866,000	3,304,000	4,506,658	541,114	12.0	16.4	408,000	133,114